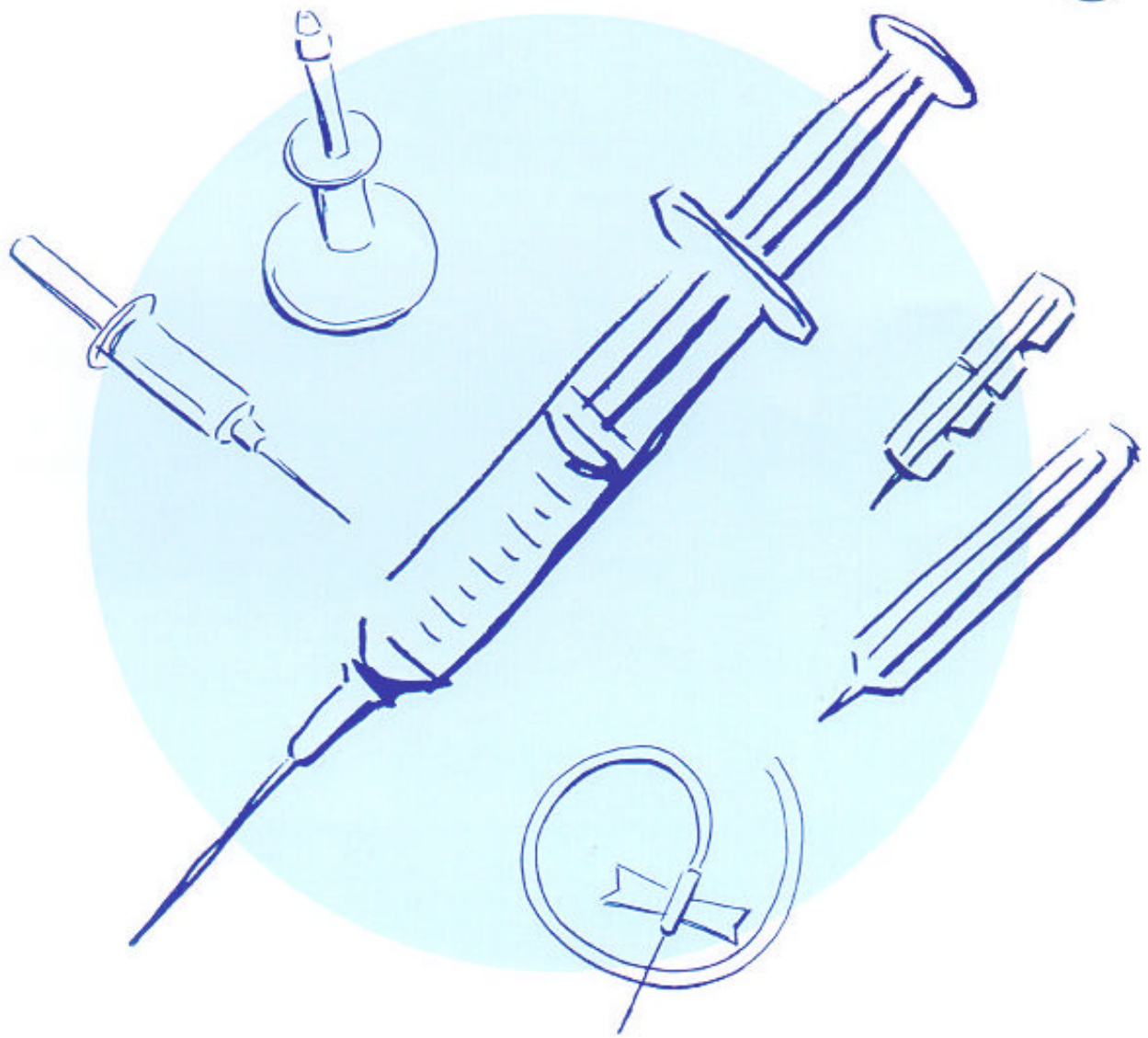


vital to health?



a briefing document
for senior decision makers

Vital to Health? A Briefing Document was funded by the U.S. Agency for International Development (USAID). The product was prepared under the auspices of the Health Technical Services (HTS) Project (Contract No. HRN-C-00-93-00001-00) of TvT Associates, Inc. and The Pragma Corporation.

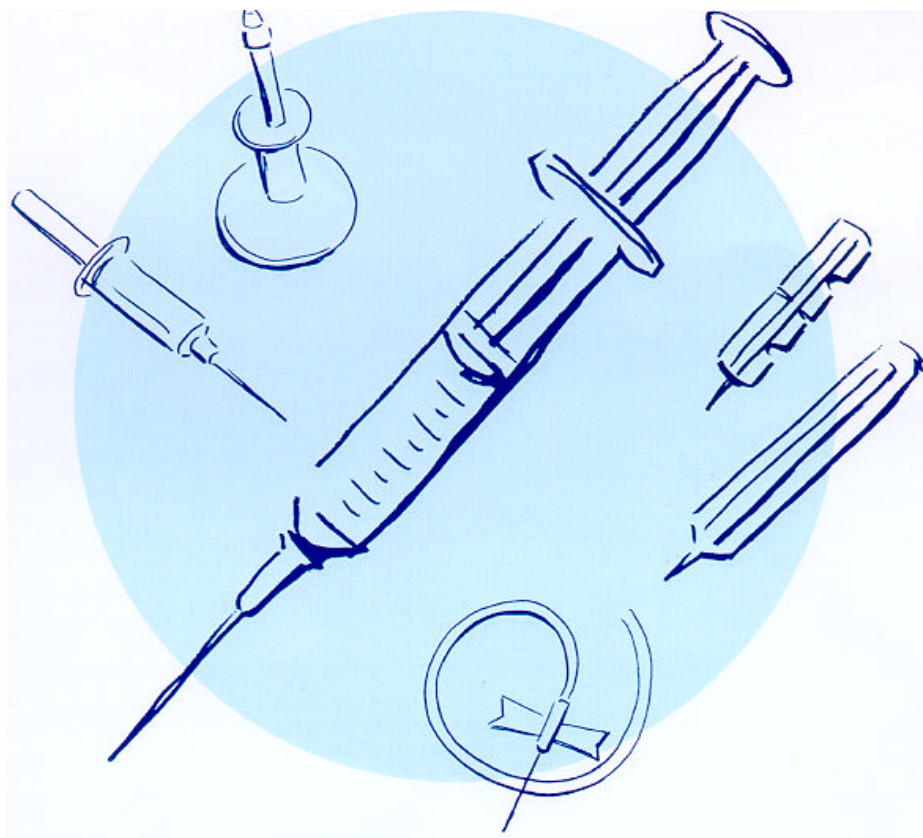
Opinions expressed herein are those of the authors and do not necessarily reflect the views of TvT, Pragma, or USAID.

VITAL TO HEALTH?

Anthony Battersby

Rachel Feilden

Barbara Stilwell



A briefing document for senior decision makers

December 1998

Contents

1	Introduction	1
2	What does “safe” mean?	3
2.1	Safe injections	3
2.2	Safe clinical practice	3
2.3	Safe disposal and destruction	4
3	Illustrations of clinical problems	5
3.1	✗ Resheathing a disposable product	6
3.2	✗ Leaving the needle in the septum	8
3.3	✗ Changing the needle between patients	9
3.4	✗ Multiple use of unsterile medical sharps	10
3.5	✗ Bending the needle after use	11
3.6	✗ Trying to make disposable equipment safe for reuse	12
3.7	✗ Disassembling disposable equipment for recycling	13
3.8	✗ Exchanging disposables One-for-One	15
3.9	✗ Misusing sharps containers	15
3.10	✗ Unsafe disposal of contaminated medical sharps	16
3.11	✗ Using medical sharps for the wrong medical purpose	18
3.12	✗ Using medical sharps for non-medical purposes	18
4	Safety standards change	20
4.1	Flaming the BCG needle does not make the injection safe	20
4.2	Boiling in an open pan does not kill all pathogens	21
4.3	Clipping off the needle or burning it off creates contamination	22
4.4	Chemical disinfection is not recommended for injection equipment	23
4.5	Open burning or burying plastics creates environmental pollution	23
4.6	Current definitions of standards	26
5	Illustrations of system problems	30
5.1	Absence of sharps containers	30
5.2	Supplies run out	30
5.3	Sharps in rubbish	31
5.4	Transferring disease	32
5.5	Sharps are valuable	34
5.6	Suitable equipment is not readily available	37
5.7	Mixed strategies cause confusion	38
5.8	Health workers allow standards to fall	39

5.9	Injections in the private sector	40
5.10	Records	41
6	Ways to lower the risks	42
6.1	Changing prescribing habits	45
6.2	Investing in practice development for staff	45
6.3	Supportive supervision	46
6.4	Social mobilisation	47
6.5	Operations management	47
6.6	Funding	47
7	Consider the circumstances	49
7.1	Behaviour	49
7.2	Management	51
7.3	Finance	52
7.4	An illustration of the comparative levels of effort and attention	54
7.5	What are your options?	54
8	Your next move	55
	Guidelines for the Task Force	55
9	Case studies	58
	References and documents consulted	66
	Contact addresses	68
Annex 1	Options offered by technology	A-1
Annex 2	Costs	A-10

Glossary

AEFAPP	Adverse Events Following Any Parenteral Procedure
AIDS	Acquired immune deficiency syndrome
Audit trail	Mechanism that makes it possible to trace what has happened to waste products.
BBC	British Broadcasting Corporation
BCG	Bacillus Calmette Guerin (vaccine for tuberculosis)
BEPO	Best Practicable Environmental Option
CBoH	Central Board of Health Zambia
CDC	Centers for Disease Control, Atlanta, USA
CDC	Communicable Disease Co-ordinator (South Africa)
DDP	Delivered Duty Paid
DPT	Diphtheria, Pertussis, Tetanus Vaccine
DT	Diphtheria Tetanus Toxoid
DWAF	Department of Water Affairs and Forestry
EPI	Expanded Programme on Immunisation
GRE	General Refuse Equivalent
HbeAg	Hepatitis B e antigen
HIV	Human Immunodeficiency Virus
H ₂ O	Water
LCV	Low calorific value
Ltr.	Litre
MCH	Maternal and Child Health
MD	Medical Doctor
MEC	Member of the Executive Council (South Africa)
MOH	Ministry of Health
ml	Millilitre
NHC	Neighbourhood Health Committee
PP	Parenteral Procedure
TST	Time Steam and Temperature indicator
TT	Tetanus Toxoid Vaccine
TTT	Time Temperature and Turbulence
UK	United Kingdom
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
Volatiles	Volatile compounds released from waste during combustion before they are ignited.
WHO	World Health Organisation
WPR	WHO's Western Pacific Region

1 Introduction

Safety of injections and other parenteral procedures must be achieved and maintained to avoid spreading disease and harming patients. There is accumulating evidence that injection equipment and other medical sharps - such as lancets, and butterfly needles on intravenous drips - provide a formidable vector for transmitting disease (Kane *et al.*, 1997). Three separate studies that examined the effect of a single needle stick contaminated with hepatitis B (HbeAg) found that the incidence of seroconverting was 19%, 33% and 80%. (*op cit*). Iatrogenic infections of this type are almost impossible to attribute to a particular parenteral procedure, partly because some patients have experienced many such procedures, and partly because the unseen bacteria and viruses inside the syringe, up the needle, or on the lancet take their time to manifest their full effects. In the case of hepatitis B it may be 20 or 30 years before the initial infection, which is frequently sub-clinical, completes its progress towards cancer or cirrhosis of the liver.

The dual problems of **time lag** between infection and symptoms, and **invisibility** of the pathogens within the medical equipment, place heavy responsibilities on all those responsible for safety of injections and other parenteral procedures. These responsibilities extend far beyond the person who gives the injection or takes the blood sample, and include supervisors and tutors imparting knowledge and skills, those responsible for resupply through procurement, stock management and distribution, those responsible for financial allocations, and all involved in disposal and destruction of contaminated waste, including cleaners, incinerator operators and public health and environmental safety officers.

This briefing document seeks to provide information on all of the aspects mentioned above. Current problems with misuse of medical sharps are illustrated to alert the reader to what may be found if you look, ask, listen and respond with follow up questions that fit the circumstances.

This document is not a “how to” manual for administering safe injections or specifying tender documents for incinerators. Instead, it illustrates processes through which the complete anatomy of problems can be appreciated, and then based on that holistic comprehension of the effects and their causes, it suggests an approach for developing the most appropriate and feasible solutions for a particular setting.

We have assumed that information on best clinical practice is available to countries. We appreciate that information on safe incineration may be more difficult to find. We welcome feedback on what is presented and what is missing; contact information is given after the references. The issue of safety of injections and other parenteral procedures affects everybody (when did a member of your family last have an injection) yet it is nobody's job. This is a first step in addressing the issue in an holistic manner.

After presenting a definition of “safe” for this context (Chapter 2) we show that however sophisticated the technology, medical sharps are misused in practice (Chapter 3). In order to achieve safe practice, behaviour, management and resource provision must be understood, and appropriate remedies identified and implemented. Safety standards are continuously being updated as research reveals more about iatrogenic infection and environmental pollution (Chapter 4); this means that minimising the risks is a continuing process. Updating knowledge, skills, policies and standards are part of this process. Solutions for some of the problems are available, but for others the best option at present is to choose the least harmful alternative until better options become available (Chapter 5). The particular range of problems and constraints vary between countries, but under any circumstances there are ways of lowering the risks resulting from unsafe practices (Chapter 6). The best approach depends on the profile of relative strengths and weaknesses in behaviour, management and finances in a specific setting (Chapter 7). The cost of providing supplies and equipment for each technical option varies enormously; our estimates show that conventional disposables are at least five times more expensive than sterilisables (Annex 2 has the details).

The next step is to approach the matter with a multi-faceted task force, involving practitioners from all fields of medical and dental services. The task force will be responsible for assessing all aspects of how medical sharps are used, the causes of any problems identified, and proposing ways to minimise the risks (Chapter 8). To illustrate the processes of disentangling complex situations, the document concludes with some case studies (Chapter 9).

If it takes you an hour to read this document, in that time over 1,000 people will contract bloodborne hepatitis or HIV through dirty injections given by health services. Thousands more will develop abscesses.

Always remember that the key defining issue is respect for duty of care - “First, do no harm”

2 What does “safe” mean?

The parenteral procedure is a very efficient way of getting medical substances - drugs, vaccines, life-saving fluids - into people's bodies. If we have to give injections, use drips and carry out diagnostic procedures, then we also have to make sure that the only things that go in during the medical procedure are the substances that we intend to administer. Safe handling of syringes and other medical sharps is vital to health.

2.1 Safe injections

WHO defines a safe injection as one that:

- does no harm to the recipient
- does not expose the health worker to avoidable risk
- does not result in waste that puts other people at risk

2.2 Safe clinical practice

In clinical practice, it is vital to observe universal precautions. When staff apply this concept, they assume that all patients may be infected with bloodborne pathogens, and must be treated accordingly.

The injunction to “observe universal precautions” has been emphasised and repeated in response to the AIDS epidemic and the spread of hepatitis B and hepatitis C, as well as haemorrhagic fevers.

As every injection involves a certain level of risk to the patient, one aspect of safe clinical practice is to ensure that only necessary injections are administered.

Whatever technology is used, everyone who administers injections must follow safe injection practices. The examples below show safe practice applied while immunisations are being given to children and injections to women.



Sterilisable syringes and needles used to give injections

2.3 Safe disposal and destruction

Medical sharps are contaminated after use and must be disposed of safely. At the time of disposal they must be placed in a puncture proof container, called a sharps container, made of either cardboard or plastic. The full sharps containers must then be destroyed.

The satisfactory destruction of clinical and sharps waste is one of the biggest problems facing health services today. Research and development are still needed to find inexpensive and acceptable ways of destroying clinical and sharps waste.



The principles of safe incineration are summarised by **TTT**:

- **Time:** long enough for complete combustion of initial waste and its volatiles and exhaust gases
- **Temperature:** between 800°C and 1,000°C
- **Turbulence:** The process of completely mixing oxygen with the volatiles released in the combustion chamber which is essential if complete incineration is to be achieved.

For an incinerator to work efficiently it must be loaded with a mixture of waste. Each type of waste has a different calorific value, known as its General Refuse Equivalent (GRE). Plastic has a high calorific value, and must be combined in the correct proportions with waste of low calorific value (such as bandages) to achieve safe and effective incineration. To mix waste correctly, it must be segregated into categories. Proper segregation can only be done at the point where the waste is produced. The minimum segregation is into three categories:

1. Syringes and other medical sharps in puncture proof containers
2. Clinical waste
3. General waste













Some countries have excellent environmental codes or legislation that provide clear guiding principles for clinical waste management. For example South Africa has a three-part policy:

- An holistic approach: waste destruction must not simply move contamination from one environment to another
- The polluter must pay
- No bad legacy: today's actions should not leave behind problems for future generations.

In this context, the polluter is the provider of health services generating the waste.

3 Illustrations of clinical problems



Bad practice includes injecting into the wrong site (for example infant immunisations into the gluteal muscle) and the wrong type of injection (for example subcutaneous instead of intradermal for BCG). Here we focus on other aspects of bad practice in primary health care, that is faulty injection technique (leading to contamination of either the injectable product or the needle) and other misuses of injection equipment.

-  resheathing a disposable product before use
-  resheathing a disposable product after use (including resheathing before putting in the waste)
-  multiple use of contaminated medical sharps
-  changing the needle between patients
-  changing the needle between drawing up the injectable and administering the injection
-  removing the needle from the syringe before disposing of it
-  bending needles after use
-  trying to make used disposable equipment safe for reuse
-  disinfecting and disassembling disposable equipment before recycling the plastic
-  repackaging unsterilised medical sharps for resale
-  misuse of sharps containers
-  using medical equipment as paperwork aids (pinning papers together), toys, darts, etc

The remainder of this chapter illustrates misuses of medical sharps, and suggests some approaches for remedying the situation.


3.1 Resheathing a disposable product

Needle stick can occur at any time but most frequently happens when staff try to resheath a needle.

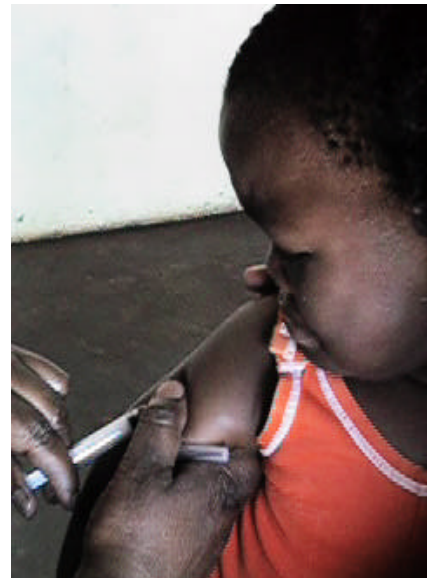
-  If the needle stick injury is **before** the injection (as shown in the picture) then the health worker may infect the patient.
-  If the health worker gets needle stick **after** the injection then he/she is at risk of contracting a bloodborne pathogen from the patient.

Case Study 5 in Chapter 9 illustrates how such misuse of medical sharps may be linked to shortcomings in management and resources.

When the health worker removed the needle sheath, why did she hold on to it? Probably because she intends to resheath the needle after giving the injection.

-  One unsafe practice often accompanies another; the health worker is also touching the needle so any contamination on her hands is being transferred into the child, who is thus exposed to avoidable risk.

If resheathing is unavoidable, then the 'one-handed technique' should be used.



Many of the accidents that occur with used sharps are caused by careless or inappropriate actions immediately **after** an injection.

A physician made a house call to one of her patients seriously ill with AIDS. She wanted to save him the ambulance ride to the hospital, so she took the blood sample then and there. She did not have a sharps container with her so she decided to resheath the needle. "The needle was dangling from my finger and I could see small drops of patient blood coating the needle..."
Washington Post, August 1998

The well-intentioned health worker shown below has prepared himself for a busy clinic. He has estimated how many clients will attend, has pre-filled the syringes in readiness, and has resheathed them **(1)** to keep the needles clean.

Where there is one unsafe practice, others are often present; we have numbered them. His products include measles vaccine (foreground), DPT and DT vaccine (background). Once DT and DPT are in the syringe they are indistinguishable **(2)**, so he replaces the paper wrapper on the syringes filled with DT. During the session, some of these wrappers fall off. By the end of the session he realises that he has over-estimated the clinic attendance so he puts all the pre-filled syringes in the salad drawer of the refrigerator, ready for use next day **(3)**.

✗ This practice is very dangerous. ✗

The contents of the syringes are unlabelled **(4)**. When the syringes were pre-filled they were at ambient temperature and as the vaccine was not administered immediately, it warmed up. Some vaccines are very sensitive to temperature; these will lose potency rapidly **(5)**. Some injectables are highly susceptible to contamination (e.g. measles vaccine) and are potentially lethal when they become contaminated (Zaffran *et al.*, 1997). The picture was taken at the end of the day; these unused, pre-filled syringes were removed from the refrigerator by the assessment team. Any residual reconstituted vaccines must be discarded at the end of the session. If the health worker had observed this rule he might have realised that his strategy of pre-filling meant that he had to discard injection equipment that was never used on a client, adding unnecessarily to costs **(6)**.



The supervisor should emphasise the following safe practices:

- Draw up the injectable product when the client is ready. Use the same needle to draw up and to inject and do not resheath between drawing up and administering the injection (addresses points 1, 2, 6)
- Keep vaccine between 0°C and 8°C during session and discard reconstituted vaccines at the end of the session or after 6 hours (point 3)
- Keep heat sensitive products in the vial in a vaccine carrier until client is ready (4, 5)

Remedy

An assessment of injection safety may identify a multitude of other problems. Those described above suggest that in-service training has been ineffective and that there is a lack of interactive, on-site supervision.

Possible approaches for remedying the situation include

- ensuring that supervisors are able to give on-the-spot education
- peer-to-peer transfer of safe practice skills and behaviour
- in-clinic discussion and group problem solving
(topic for discussion: why are our clinics so crowded?)

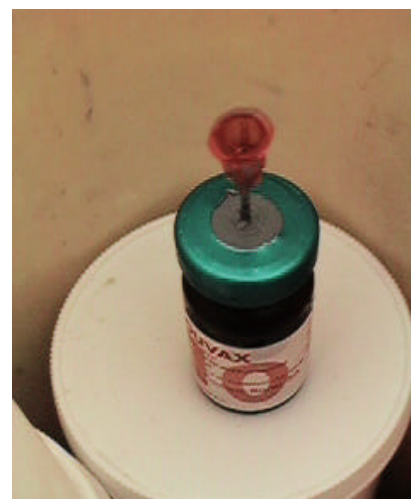
One example of the latter is the “Triple A Approach” - Analysis, Assessment, Action - which has been used in Zambia as a method of identifying problems and choosing interventions that will improve quality. For example a Sister-In-Charge at an urban health centre said that her staff had identified overwhelmingly busy clinics as a problem, and their analysis located one cause of the problem as the late arrival of the registration clerk. Addressing this source of the problem prevented a backlog of clients from accumulating, and eased the pressure of work.

A desire to reduce such pressure was one factor in the pre-filling episode shown in the picture above.

3.2 Leaving the needle in the septum

Here the needle has been left in the septum of the injectable. This leaves the product fully exposed to the environment and to the risk of contamination. Changing the needle between drawing up and administering the dose provides a further opportunity for contamination. It is also wasteful, and therefore more costly, because it uses an extra needle for drawing up. It is a WHO recommendation that the needle should not be left piercing the septum.


The needle used to administer the dose should also be used to withdraw the product from the vial.



Studies carried out by Becton Dickinson show that although it is possible to measure the difference between the sharpness of a needle that has previously pierced a septum and one that has not, the difference is so minuscule that it would be “barely recognisable while using the cannulae with patients” (Becton Dickinson, 1997).

3.3 Changing the needle between patients

WHO has shown that changing needles between patients but using the same syringe is just as dangerous as using the same needle and syringe on different patients (WER, 1987).

 “Governments and agencies make blatantly insufficient budgets for syringes and, to save money, they sanction instead the purchasing of many more needles than syringes which they assume to be re-used.” WHO/EPI 1997

Changing needles does not prevent body fluids from entering the barrel of a syringe, so injecting a second patient with the same syringe is a very dangerous practice, especially when staff have aspirated to check that the needle is not in a blood vessel. Even a release of pressure on the syringe piston is enough to allow body fluid to pass back up the needle into the syringe. Only 0.04 microlitres is required to transfer Hepatitis B (BMA 1992). The equivalent of the volume of fluid needed to print a full stop is sufficient to infect 12 people. The hepatitis B virus is also able to survive outside the body for at least a week.



Remedy

When procuring disposable syringes and needles buy enough to meet demand and buy the same quantity of needles and syringes.

Chapter 6
describes more
ways to lower
the risks.

3.4 Multiple use of unsterile medical sharps



The picture on the left was taken in the treatment room of a clinic. It shows three syringes that have been used to give at least seven injections. Note that one syringe has been resheathed and the other two have not.

Sometimes multiple use results from staff ignorance. For example in one Eastern European country a nurse was busy injecting 16 infants, in the ward, all from the same syringe and needle. When asked why she was doing this she replied, *"It's alright, I'm injecting antibiotics."*

Syringes and needles are not the only pieces of parenteral equipment to be misused. Lancets, butterfly needles and drips are commonly reused. In many societies infusions are extremely popular. The picture on the right shows a drip stand found in a clinic, with the used needle exposed and a partly used infusion ready to be used up on another patient. The far pictures shows a partly filled infusion bottle lying in a public place, while the lower frame has an exposed butterfly needle lying in the gravel outside a clinic entrance. These are just as serious environmental pollutants as needles and syringes.



The two lancets on the left have been used to collect blood slides for malaria. They are standing in a small bottle of water. When this picture was taken, they had been used on a total of 64 patients


3.5 Bending the needle after use

In an effort to prevent the reuse of contaminated sharps people sometimes come up with dangerous 'solutions' and inappropriate advice, such as that cited here in a manual dated 1996.

“Safety Tips for Single Use Needles and Syringes:
When single-use disposable syringes and needles are used, it is important that:

*Each needle and syringe is used only once.

*Needles and syringes are not disassembled after use.

 *As per... instructions needles are bent and syringes are crushed prior to recapping and disposal.

*They are properly disposed of in a puncture-proof container.

*Adequate supplies of syringes and needles are maintained.”

Source: A family planning manual in a South East Asian country.



The third point results in the practice illustrated that puts workers at risk.

Remedy

What this system needs is:

- Sharps boxes in sufficient quantities for every worker performing parenteral procedures to have one beside his or her place of work
- A secure, audited disposal and destruction system which is the final essential component in any system that uses disposable technologies.

Chapter 6
describes more
ways to lower
the risks.

3.6 Trying to make disposable equipment safe for reuse

Used disposables are contaminated and cannot be sterilised because they are made of a different grade of plastic than that used for sterilisable syringes. A disposable syringe will melt at the temperatures required to kill pathogens. Health staff who have tried putting conventional disposables in their steam steriliser have discovered how tedious it is to remove melted plastic from the pot, so they resort to boiling the used disposables instead.



The picture shows syringes in a boiling pan. How many problems can the observer identify? (1) The syringes are disposable; they no longer have their wrappers, therefore they are no longer sterile. (2) They are being boiled, rather than exposed to steam at 121°C. (3) They have not been disassembled and so the pockets where dirt becomes trapped cannot be cleaned. The worker, who was boiling them said,

“The problem with these syringes is that half way through the injection the seal fails and the injectable squirts up your arm.”

If a high temperature is reached then the plastic melts. The health worker who had the problem shown on the right said: ***“If we try to sterilise the syringes they melt, so we change the needles.”*** Needle changing between injections is a very dangerous practice which provides no protection whatsoever. Any contamination that is in the needle is drawn into the barrel of the syringe, and injected into the next patient.



Remedy

- Find out why health workers do these things.
 - Were they taught them during their pre-service training?
 - Have they picked up unsafe habits from their colleagues?
 - Do they have a logic of their own for doing what they do?
 - Have they had any in-service training to keep them up to date with changing technology and safer procedures?
- Do they know that their practice is dangerous and do they understand why?
- If they know what is safe, why are their practices unsafe?
- Will a change in behaviour supported by better supervision correct the problem?
- Are more supplies or equipment needed?
- Now decide. Is this:
 - a knowledge or behaviour problem
 - a management problem
 - a resource or financial problem
 - two or more of the above

3.7 **Disassembling disposable equipment for recycling**

Some countries have introduced systems for disinfecting used disposables before they are discarded. This is not good practice.

- First, it requires the staff to handle the used devices, thus **invalidating** one of the major advantages of the disposable, namely that it does not have to be handled after it is contaminated.
- Second, while some staff may handle the used product as specified, many will not, and their mishandling will create a risk for themselves and for others.
- Third, it requires a supply of bleach or some other disinfectant, which must be diluted correctly.
- Fourth, it requires a secure holding and collection system to ensure that material for recycling does not get reused as syringes.

The instruction for staff to disinfect used disposables appears to stem from three realities:

1. The country lacks equipment for destroying the contaminated waste.
2. There is a perception that it is wasteful to discard high quality plastic (used only once for clinical purposes) which could be made into other things.
3. The risks for staff handling the waste are inaccurately assessed, or ignored.

The country where the following pictures were taken had just moved from sterilisable syringes to disposable syringes, which generate vastly greater quantities of waste (see Section 4.5). There was a desire to make something useful out of the high quality plastic rather than simply throwing it away.

The illustration shows huge quantities of used syringes; they have been carefully washed and sorted. Note that there are no needles; they have been taken and recycled for use. Two of the benefits of disposable syringes have been eliminated by the official instructions because:-

- 1)** Staff time is taken up on cleaning, storing and transporting the syringes to a recycling centre; and
- 2)** Staff are placed at risk by handling contaminated equipment that was designed for instant disposal.



Soaking disposable syringes:

The health worker is at risk. In addition a supply of bleach is required and the dilution must be correct to be effective. Contrary to common belief a stronger concentration is not better; bleach can kill treatment drugs (such as antibiotics) if handled carelessly. Unlike sterilisables, the disposable technology relieves staff of the discipline of using forceps. At the end of the bleaching cycle the worker has to fish for the syringes, needles and vials in the bowl, with a high probability of needle stick.

Workers at a recycling plant received the syringes shown on the right without the careful cleaning shown in the picture above. The store contains large boxes piled high and overflowing with used syringes, the needles still attached. The workers did not mind because they could use the syringes and needles to play darts (see the box on the right).



As one health worker in that country said

“Why should we take risks when the money we get paid for them does not even cover the cost of petrol to send the used syringes to the factory? It is just a waste of time.”

The benefits of recycling the plastic from used syringes have not been demonstrated. The full costs include not only health service resources - including personnel time, bleach, finding storage space until transport can be found to return the cleaned syringes to the recycling plant - but also infections from needle stick. It is likely that these costs greatly exceed the benefits accruing from the recycled plastic products, the creation of which consumes even more resources.

3.8 Exchanging Disposables One-for-One

In some countries staff have to hand in the used syringes to receive replacements on a one-for-one basis. The illustration shows how one nurse had solved the problem of accounting for used syringes. Note the caps lying next to the piece of ‘styrofoam’ so that she can resheath them all at the end of the morning after the syringes have been accounted for. Managerial requirements such as this are not necessary and put clinic and stores staff at risk. See section 5.10 for examples of ways to keep track of injections performed.



3.9 Misusing sharps containers



Proprietary sharps containers are by their nature well made and so in societies where robust containers are in short supply they are valuable for other purposes. Staff may not want to ‘waste’ them by destroying them after they have been filled once. In the example on the left the container has been kept open so that it can be overfilled, emptied and then reused. Note that the health worker carefully resheathed all the needles, thinking he was reducing the risk of needle stick. He has put himself at great risk; he has also put the person emptying the container and anyone else who comes into contact with the contents at risk because the contents are accessible.

Even where sharps containers are provided, they may not be used correctly. Focus group discussions conducted at a teaching hospital as part of a study of health workers' perceptions of health risks revealed that doctors throw used medical sharps in the general direction of the sharps container and people working in the area get needle stick injuries on their feet. In this environment some staff would rather resheath the needle to protect the person who disposes of the sharps container.

Remedy

Under the duty of care principle, it is the responsibility of the person who used the equipment to ensure that it is disposed of properly.

When sharps containers are first provided in a health service, staff need to be taught the correct way to use them.

3.10 Unsafe disposal of contaminated medical sharps



Inappropriate waste containers, such as the one shown on the left, are another cause of needle stick. Not only is the health worker at risk, but so is the cleaner when he or she empties the container. As the workers at a hospital in Southern Africa said, ***"We wear gloves because we fear all the needles in the rubbish"***

Indiscriminate disposal of used sharps in the general waste to be taken away by the municipal refuse collection provides a further cause of needle stick.

"Recently I pricked my left hand, it swelled up and I had to go to hospital and have injections for many days" said a municipal refuse worker after suffering needle stick.

"Yes there are syringes and needles in the trash, yes we prick ourselves, but it is our job" explained another refuse worker as he threw an open box of trash from the health centre into the collection vehicle.



Remedy

It is the responsibility of the person who carries out a parenteral procedure to show that waste has been safely destroyed.

At present there are no inexpensive environmentally acceptable incinerators, but field trials are expected soon. In the mean time, if the health service cannot invest in the incinerators that are available, waste must be destroyed by:

- Provision of a secure and cleanable site where contained incineration can take place (e.g. using an oil drum)
- Witnessed burning, i.e. more than one person can confirm that incineration has taken place
- Maintenance of an incineration register
- Observing local environmental regulations (where they exist)



Disposal of clinical waste, including sharps, is often a neglected subject. This picture shows the waste chute of a hospital in Eastern Europe, festooned with infusion tubes and catheters. Used syringes litter the ground at the base. The waste chute is five storeys high and presents a major hazard for anyone who might try to clean it. In addition the whole area is accessible to the public.

"My biggest clinical problem is gas gangrene" said the director of this hospital as he showed the assessment team round the sterilising department; half of the autoclaves were not functioning, the other half were running well below pressure, and the staff were eating their lunch on the work top. In the sterilising department of an adjacent hospital one of the broken hot air ovens was being used to store bread.

Those responsible should ensure that equipment remains in working order.

Ancillary staff also have a duty of care.

Chapter 6
describes more
ways to lower
the risks.

3.11 Using medical sharps for the wrong medical purpose

In many countries malaria slides are collected as a matter of routine. The picture on the right shows a malaria worker's box. It contains the sharps he uses as finger prickers, and his slides: those awaiting diagnosis at the top and bottom, and the clean ones in the middle. He was originally issued with the Hagedorn lancet (top pointer) attached to a cork stopper that fitted the top of a glass bottle of spirit in which the lancet was disinfected between patients. The bottle has long since been broken and he now uses the 4 disposable hypodermic needles (one sheathed) plus the Hagedorn shown in the picture. He has no way to sterilise these as he goes around the community making thick and thin smears. The box contains a total of 12 blood slides collected with his 5 finger prickers.



Finger prickers are designed to enable the health worker to take a small blood sample. Hypodermic needles have a channel through which the injectable product enters the body; they are designed to minimise bleeding. If channelled sharps are used as finger prickers some of the patient's blood will remain inside the equipment. Furthermore, without a syringe the hypodermic needle cannot be flushed and cleaned, and without a steriliser even the purpose-designed equipment cannot be made safe.

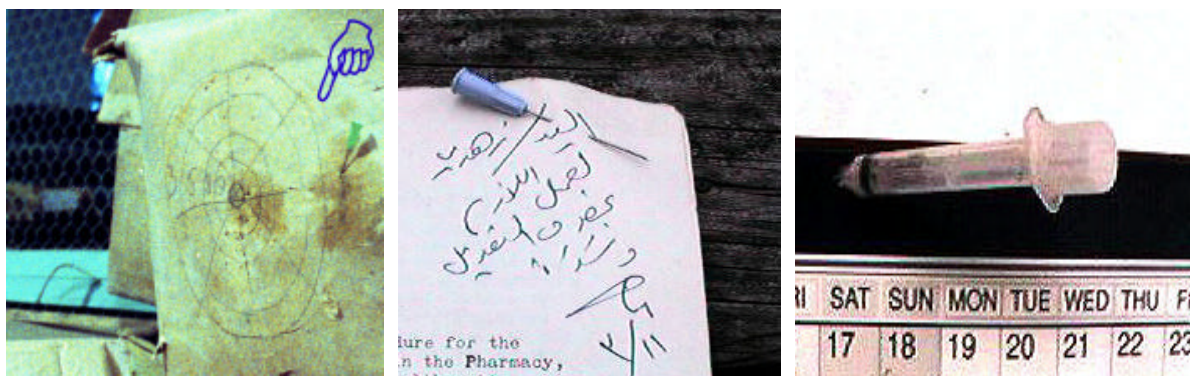
Remedy

Health workers should use only sterile lancets or solid needles as finger prickers. They must sterilise their finger prickers after a single use.

More remedies are discussed in Case Study 2 in Chapter 9.

3.12 Using medical sharps for non-medical purposes

Medical sharps are clinical items. However they are frequently used for other purposes. For example they may be used to play darts or as a substitute for paper clips, or as a drawing pin attaching notices to the wall. All these uses expose the person carrying them out and others to risk.



Remedy

Ensure that health staff have basic stationery, such as staples for the stapler, paperclips and drawing pins

Provide sharps boxes for medical sharps, and an audited system for disposal and destruction

Check whether health service regulations specifically proscribe the mis-use of sharps.

When sharps get into the environment they are especially popular with children for whom they have an endless fascination. The picture on the right shows some children who are playing shops. Amongst their wares are used syringes and vials. When asked where they got them they replied,

"We like to play shops and get the syringes and little bottles from that hole over there", pointing to a gap in the wall through which the clinic's refuse pit could be seen.

A barefoot child was asked why he was playing on the town rubbish dump. He replied,

"We play with syringes in the dump, it's fun, we prick each other for a laugh."

Clinic staff may even contribute to the problem. At one health centre the staff said, ***"We give the used and part used vials to the children, they like to use the bottles for other things."***

Staff have a responsibility to ensure that their actions do not result in waste that puts other people at risk.



Remember, first do no harm

4 Safety standards change

As more knowledge is accumulated, practices that were once thought to be safe are now discouraged or proscribed:

- ☒ flaming the BCG needle
- ☒ sharpening sterilisable needles used for routine injections
- ☒ boiling in an open pan
- ☒ chemical disinfection
- ☒ clipping off the needle
- ☒ burning off the needle
- ☒ burying contaminated waste
- ☒ open burning of plastics

Safety standards become more stringent as we learn about emerging diseases and analyse the side effects of current practices. Our best judgement about what is safe today may have to be reassessed in light of new knowledge in the future.

This means that risk reduction and improving safety is a continuous process, requiring continuing attention and effort.

4.1 Flaming the BCG needle does not make the injection safe

The procedures for intradermal injections used to be different from those for other procedures. The procedure shown on the right for BCG immunisations was set down in the original 'Blue Book' issued by WHO for the immunisation programme (EPI) in the 1970s. At that time there was less knowledge about the risks of disease transmission. Technologies used for administering intradermal injections were expensive and difficult to use.



Sterilizing by flaming

After you have finished injecting each child and before you inject the next you must sterilize the needle by flaming:

- (1) Do not remove the needle from the syringe.
- (2) Put the point of the needle in the top of the flame of the spirit lamp and hold the tip of the needle over the flame till it starts getting red. This will take about two seconds. Do not let the needle become red hot.
- (3) Expel a few drops of vaccine (keeping the needle down).
- (4) You are now ready to inject again.

If the syringe has been emptied by the last injection you should flame the whole needle (up to the hub) and then refill the syringe as already described.

The confusion left behind by having different procedures for injections remains to this day. During a meeting at WHO in 1998 a senior representative from a country in the Western Hemisphere remarked ***"You do not have to worry about injection safety in my country."*** When asked ***"How do you give BCG?"*** he replied, ☒ ***"We change the needle."*** ☒

We now know that this procedure does not make injections safe. As our knowledge expands, safety standards change. It is essential that all staff and trainers keep their knowledge up to date.

Remedy

Review your basic curriculum and training manuals: do they describe up to date practice?

What are the systems for ensuring that national regulations and procedures reflect current known best practice?

What systems exist to ensure that staff are trained to follow new procedures when they are introduced?

How many staff need updating now?

4.2 Boiling in an open pan does not kill all pathogens

In the past, boiling at 100°C was considered a suitable means of making equipment safe for reuse. Boiling will destroy some pathogens but does not kill bloodborne hepatitis viruses and bacterial spores. Therefore boiling is not an acceptable method of ensuring that reusable equipment is safe.

Boiling does not require specialist equipment. Any vessel that can be heated may be used, although purpose designed ones may make the task easier. However, at best boiling can only achieve high level disinfection if it is applied for 20 minutes at 100°C. At worst it may achieve almost nothing, particularly if boiling takes place at higher altitudes where water boils below 100°C.

In 1985 Martin and Bartzokas carried out a study of 31 boiling apparatuses from dental practices in UK, testing them for their ability to disinfect. Each apparatus was run through 20 cycles and the contents were then tested for the presence of micro-organisms. The result was that all 31 failed to sterilise, and 81.8% of the micro-organisms that were present at the beginning of each cycle were found still alive at the end of the cycle. Here is a list of the human pathogens that were found among the micro-organisms:



Gram positive cocci	Bacilli	Clostridia	Gram negative
Staphylococcus aureus Staphylococcus albus Micrococci Streptococci viridans Streptococcus faecalis	Lactobacillus acidophilus Gram-negative bacilli (unidentified) Aerobic spore-forming bacilli (unidentified)	Clostridium perfringens Clostridium tetani	Escherichia coli Klebsiella spp.. Pseudomonas aeruginosa Gram-negative bacilli (unidentified)

The paper in which this study was published also reported finding bloodborne hepatitis virus in the samples that had been boiled. The results of this study conflict

with the theory that most human pathogens are killed after boiling at + 100°C for 20 minutes. The study found that the average temperature reached during the cycles was 89.6°C and the maximum was 98.8°C, i.e. a full rolling boil was not achieved.

Another disadvantage with boiling is that staff can easily add and withdraw items from the boiler during the cycle, thus further reducing the effectiveness of the procedure. If boiling is carried out in hard water, calcium salts will be deposited and these block hypodermic needles and prevent syringes from working. There is no technology for preventing this problem occurring with open boiling.

Boiling is better than doing nothing but it should not be considered a satisfactory way of achieving safety.

 Boiling is no longer considered to be a means of making equipment safe. 

4.3 Chemical disinfection is not recommended for injection equipment

In some health services, chlorine based compounds (most commonly bleach) or sodium hypochlorite (often known as Milton) are used to kill germs. Chemical disinfection is not recommended as a method for making used syringes and needles safe (WHO/AIDS 1988). The reasons are:

1. To be effective bleach must be used at the correct concentration: usually 0.5% diluted in drinking water (which may be in short supply). This requires the worker to make a measured dilution, which is frequently not done. As one health worker in Southern Africa said, *"I lost my measure a long time ago so I just tip a bit in."*
2. Bleach is inexpensive but has many domestic uses and may be taken by workers for other purposes. In one Eastern European country staff were unable to complete the disinfection phase of their health service's recycling strategy because the health centre had run out of bleach (see Section 3.7 on disassembling and soaking).
3. To be effective, chemical disinfection requires that the "2x2x2" method be followed: rinse in drinking water (that may be in short supply), flush with bleach, rinse with drinking water. If drinking water is not used then organic matter in the water may deactivate the bleach. If the second rinsing is not carried out then the efficacy of the injectable may be compromised, especially live vaccines and antibiotics.
4. Bleach is highly corrosive and may damage needles and syringes after a few disinfecting cycles.
5. Bleach can be an irritant to the skin and mucous membranes, and extremely harmful if ingested by the patient. If nasogastric tubes are disinfected in bleach and not properly rinsed, patients may accidentally

have bleach introduced into the stomach. Therefore it may be a priority to buy disposable tubing.

6. Bleach stored in its concentrated form is hazardous especially at the high temperatures often found in clinic store rooms.
7. For some services, for example dentistry, where the preferred presentation for local anaesthetic is a cartridge, it is not possible to aspirate and so flush the needle.

✗ Chemical disinfection is not recommended. ✗

4.4 Clipping off the needle or burning it off creates contamination



There are several proprietary devices for destroying needles at the point of use. In the past needle clippers were supplied by donors and frequently used, but as one nurse in the Middle East observed,

“They very quickly become wet and we worry that they will spread infection.”

She was correct and this is why

✗ needle clippers should not be used. ✗

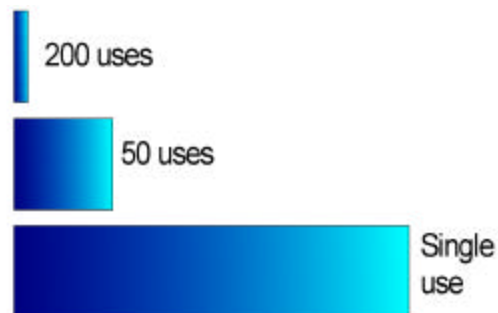


Needle destructors such as the one shown above burn the needles; unlike the needle clippers, these devices all require electricity.

A needle destructor can become contaminated both on the top and around the catchpot for the burnt needles, because fluid can run out of the syringe when the needle is stripped as shown in the picture on the left. Both areas can be a source of cross contamination.

4.5 Open burning or burying plastics creates environmental pollution

In the past, sterilisable syringes were made of glass; after a final sterilisation cycle they could be discarded with other waste into conventional dumps. The modern plastic sterilisable syringe cannot be discarded in this way because the plastic will neither rot nor degrade naturally; therefore it must be destroyed. When using disposables the quantities of waste are much greater.



Comparison of waste volumes for sterilisable syringes used 50 or 200 times and disposables used once.

The useful life of sterilisable needles used to be extended by sharpening them, but this is no longer recommended, except for special needles (e.g. for lumber puncture). When sterilisable needles become too blunt for use, they can be sterilised for the last time. Although they are not contaminated they can still cause harm if discarded into the environment. They must be disposed of safely in puncture proof containers designed for the purpose.

Like the modern sterilisables, disposable syringes are made of plastic. They are made from non-chlorine based plastic which does not produce dioxin when burned. After use it is intended that they should be incinerated at a high temperature (800°C), to avoid the unpleasant by-products of noxious gases. This high calorific value waste, together with the steel sharps, needs a mix of low calorific value organic waste to make it burn properly, enabling the incinerator to reduce it all to a small pile of ash. This incombustible residue is sterile, non-toxic, and can be dumped or taken away by the refuse removal system.

Standards for disposal and destruction have been altered in response to changes in the characteristics and composition of clinical waste, and to increasing awareness of environmental pollution. As countries establish clean air regulations and tighten laws protecting water resources, uncontrolled burning and burying waste in pits are increasingly regarded as unacceptable methods of disposal. For example South Africa has a Water Act (1956) and an Environmental Conservation Act (1989), which set down requirements based on three guiding principles:

1. Duty of Care “The organisation that produces waste carries, under all circumstances, the ultimate responsibility for the fate of generated waste. The Generator will incur a duty of care that is owed to society.” (DWAF [Department of Water Affairs and Forestry] 1994)

2. The Polluter Pays “The polluter pays principle ensures that the Generator of a waste always retains the ultimate financial responsibility for ensuring that the waste is handled, stored, transported and disposed of according to the legislation and in an environmentally sound and acceptable manner.” (DWAF 1994)

3. The management of waste should be based on Best Practicable Environmental Option (BPEO). This includes:

An holistic approach, that is one which does not reduce the pollution in one medium, for example air, by increasing it in another e.g. water.

Emphasis on a long term solution. There should be No Bad Legacy, i.e. the present generation should not leave a future generation with a bad legacy of community health and contaminated sites or with solutions that impose an unreasonable risk or cost on a future generation. (President’s Council 1991)

In such circumstances the destruction of plastic waste creates particular problems. When the plastic from which syringes are made is burnt, it does not give off poisonous gas but it does emit very unpleasant smells when burnt at low temperatures. The noxious fumes cause nuisance, which in turn discourages the

staff from burning the waste. Many of the other products used in health facilities that are also sent for burning (e.g. detergent bottles) do emit poisonous gases such



as dioxin when burnt at low temperatures. In many places used needles are stored in empty plastic bottles such as the one shown on the left, and these may emit poisons when burnt. The concentration of needles in this way also makes it difficult to burn them. See Section 5.6.

The pit is a traditional method that is used sometimes for burying, sometimes for burning waste. In the picture on the right the pit has been dug alongside the back of the clinic wall - note the water pipe across the middle of the pit and straight edge of the clinic's foundations on the right and the syringes lying around the outside the pit. The fumes go directly into the MCH area. This is not a suitable method of disposal because: (a) it is not environmentally acceptable,



(b) it places staff at risk, and (c) it places at risk those who have access to the area.

The pit above is in the compound of a facility equipped with a modern incinerator. However, the equipment was not being used, because the facility had not bought diesel oil, on account of a cash flow problem.



The lower picture illustrates what can happen to pits during the rainy season.

We cannot expect health staff or cleaners to have the specialist knowledge required to identify chlorine-based plastics and separate those from the rest. Nor can we expect them to conjure up a fire that will burn plastics at high enough temperatures to prevent toxic fumes.

Remedy

- Supply sharps boxes at all locations where parenteral procedures are carried out

Until suitable incinerators are available:

- Provide a secure and cleanable site where contained incineration can take place (e.g. using an oil drum)
- Witness the burning of contaminated sharps, i.e. more than one person can confirm that incineration has taken place.
- Maintain an incineration register

Where local environmental regulations exist they must be observed.

In the longer term provide suitable incinerators at facility level, or establish collection systems to bring waste to suitable incinerators located nearby.

4.6 Current definitions of standards

The first three definitions come from “*Infection Control, WHO Regional Office for the Western Pacific 1990*”

Cleaning

Cleaning is the physical removal of organic material or soil from objects.

Disinfection

Disinfection kills or inhibits most but not all micro-organisms through the use of chemical germicides or boiling.

Sterilisation

Sterilisation is the complete destruction of all micro-organisms and is carried out by steam under pressure, dry heat, gas or liquid chemicals.

Disposal

Disposal is the process by which the user places a used medical sharp directly into a sharps container.

Destruction

Destruction is the process by which contaminated clinical waste (including medical sharps) is destroyed in an environmentally safe way so that it does not remain in the environment in a form that is dangerous to society.

4.6.1 Cleaning

For all methods of sterilising the most important action is effective cleaning. If organic matter, dirt, and other contaminants are left on the syringe and needle, that material insulates the viruses, bacteria, and spores and protects them from any method of sterilisation, especially chemical methods.

In addition to effective cleaning of equipment it is essential for health workers to clean their hands. This may be simply achieved by washing with soap and drinking quality water before handling syringes and needles. Clinical studies have reported 99% reduction in the number of micro-organisms on hands following proper cleaning with soap and water (Lowbury et al. 1964).

The first and most important health education message is:

“Wash your hands.”

4.6.2 Steam Sterilisation

Steam sterilisation requires specialist equipment, which is generally readily available. Sterilisers range from the simplest domestic pressure cooker up to hospital based autoclaves. The difference between an autoclave and a steam steriliser is that the autoclave draws a vacuum before admitting steam, thus ensuring complete saturation within the chamber. An autoclave also requires a regular supply of electricity.

With steam sterilisation it is not possible to insert or withdraw items from the vessel during the cycle. However, on the smaller units health workers may misuse the equipment by shortening the time that the steriliser runs at its operational pressure of 101kPa (15lbs).

Steam sterilisers and autoclaves require a supply of spare parts and when seals become worn the equipment will no longer function as designed. One country has monitored the need for spares and found that the cost is about \$0.70 per steriliser per year. The use of the TST spot (the ones illustrated come from India) does give visual evidence that the sterilising cycle has been satisfactorily completed (i.e., saturated in steam for 20 minutes at 121°C). The cost of these indicators is about \$0.008 each. Each indicator is 4.5 cms long and some health workers tear them into either half or thirds for greater economy, thus reducing the cost of demonstrating that the sterilisation cycle was completed (see Annex 1).



During a health review in India in 1998 an assessment team visited a health facility that was using sterilisable syringes. They asked the health worker how she ensured that her syringes were sterile and how she was able to assure her patients that the syringes were safe. She showed the team the sterilising register in which every sterilising cycle was recorded, complete with date and quantity of syringes and needles sterilised. Next to every record she had attached the TST indicator, demonstrating that the cycle had been successful.

Once the cycle is completed the equipment will remain sterile until the steriliser is opened. Steam sterilisers are vulnerable to the effects of hard water but this problem can be significantly reduced by using a hard water pad or virtually eliminated by a vapour purifier (currently under field trials).

Portable steam sterilisers can be used on domestic heat sources. They provide the only operationally practical method of sterilising where there is no electricity and where it is not possible to rely on steriliser drums that are sterilised elsewhere.



Vapour purifier being loaded with a steriliser drum

Sterilising is an activity that lends itself to mass production and economies of scale. Most hospitals have a central sterilising unit that serves all departments. If sterilising drums are used then the activity of sterilising can be separated from providing service; for example instruments can be sterilised in one place and used in another.

Remedy

One South East Asian country has successfully upgraded the quality of injections given during outreach by providing the teams with sterilised supplies in drums. Without this innovation each team had to take a portable steam steriliser to the outreach site and spend the first hour or so preparing the syringes and instruments before administering any injections.

Under the new system instruments are returned to the central health facility where they are cleaned and sterilised and made ready for the outreach teams to collect first thing in the morning.

The sequence of events is shown below.



Drum ready to be filled with syringes



Large steam steriliser
(non-portable)



Health worker carrying drum and other
equipment on outreach



Top: Taking syringes from the drum.
Bottom: Flushing before returning to health
clinic.

Chapter 6
describes more
ways to lower
the risks.

5 Illustrations of system problems

5.1 Absence of sharps containers

When sharps containers are not supplied, people must somehow make do. They use what is available, even when this is totally unsuitable. The illustration shows a plastic bag being used for disposal. There is great risk for anyone who touches such a container, or attempts to carry it to the place where it will be destroyed.



5.2 Supplies run out

A reliable supply system is an integral part of any health service. If sterilisable needles and syringes are used the sterilisers will need a regular supply of fuel for the heat source, and from time to time the needles and syringes will need to be replaced. Spare parts will be needed at less frequent intervals. When disposables are used, any break in supplies means that syringes run out. In the case of standard disposables, staff will be tempted to recycle used syringes. In the case of autodestruct disposables, if supplies run out the staff are faced with three choices: either resort to alternative types of syringe (which may be the wrong size and/or unsterilizable: for example administering an immunisation with the disposable 5ml mixing syringe instead of the 0.5ml autodestruct), or cancel injections, or ask patients to bring their own syringes (which may be neither sterile nor the right size). When disposables are used staff worry much more about supply because it is a more critical issue.

"I worry that I will not have enough syringes and needles" said one health worker, even though her store had enough syringes and needles to last her over six months. When the overall figures were examined it turned out that 8% of surveyed facilities were out of stock on the day of the visit, so the health worker's uncertainty had some justification.

The regular supply of sharps containers is also a bigger issue for a health system using disposables than it is for sterilisables, because the volumes of waste are about 200 times greater. (see section 4.5)

Refer to Case Study 3 in Chapter 9.

5.3 Sharps in rubbish

Syringes discarded in rubbish can harm other people, and may be recycled for profit, thus harming even more people.



Careless disposal

When used syringes are dumped, anybody who is in the vicinity is at risk. Rubbish dumps are a favourite place for children to play, for people to scavenge and for animals to graze. All are highly vulnerable, as shown in the illustrations.



Collecting used plastic including disposable syringes in Eastern Europe

5.4 Transferring disease

Syringes and other medical sharps are efficient vectors for transmitting disease. An unsafe injection is not a disease but it can transmit a multitude of infections, some of which may result in serious disease outcome.

The risk of infection from dirty injections is high. Only 0.04 microlitres is required to transfer Hepatitis B (BMA 1992). How much is 0.04 microlitres? A 0.5ml dose of infective material would be enough to transfer Hepatitis B to 12,500 people. Depending on the region of the world between 15% and 40% of injections are unsafe. (Kane *et al*, 1997). Paradoxically it is often difficult to obtain evidence that dangerous injections are being given. The reasons for this are threefold: invisibility of infection on the equipment, a high proportion of infected persons show no signs of their transmissible diseases, and a time lag, sometimes of many years, before the full consequences of prior infection become apparent.

However, an unsterile injection may have a sequel that manifests itself rapidly and clearly as an abscess. In many health services abscesses are common, but they may not appear in health service statistics. In one South East Asian country, interviews with clinic staff brought the response *"We hardly ever see abscesses"*.

Interviews in the same town with private doctors produced a very different response: *"Abscesses, I see at least two or three every day,"* said one doctor in exasperation. One of the problems is that a patient who believes that the source of his abscess is the health service is reluctant to go back to the same service for treatment. The feed-back loop so essential for effective surveillance is not connected.

An outbreak of abscesses damages the credibility of health services. Unlike many other infections abscesses appear rapidly, whether they be sterile abscesses (caused by injections into the wrong place where they were not absorbed or by too big an injection dose) or septic abscesses resulting from a dirty injection.

The following example comes from Southern Africa; the child was one of 17 casualties arising from an immunisation campaign in the primary school.

“Elisha was still in a bad way. He had a gaping hole the width of an adult's forefinger. The wound had been cleaned recently, but when we undid the bandages inside the matron's office, out came a really putrid smell of rotten flesh!

The matron, who could not be identified [said] that when Elisha first came to [the] Hospital, the lump had just ruptured and one could actually see the bone.”

BONA, September 1997



Not only did this child suffer a massive abscess; the picture shows that the injection site (his hip) was totally inappropriate.

What to do?

Abscesses represent one of the most visible indicators of problems with safety of injections and unsafe injection practices. If health services respond rapidly to adverse events following parenteral procedures, and take a problem solving (not a problem-burying) approach to address the real causes of unsafe practices, then they are likely to make progress on this difficult issue. The following flow chart is an action plan for responding to a hypothetical press report that the “**Health Service Gives Abscesses.**” The action plan was prepared by participants (their choice of format) in a course on operations management for immunisation (FBA, 1997); several participants said that similar newspaper reports had appeared in their area in the recent past.

IDENTIFYING PROBLEMS

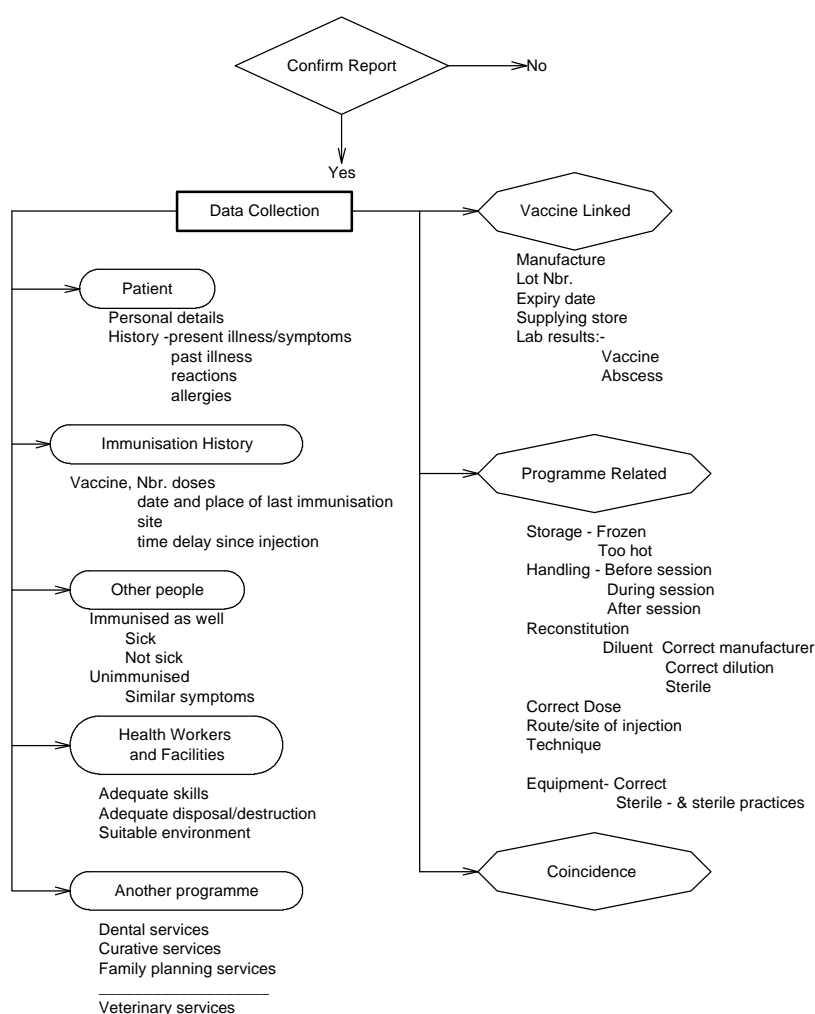
Injection Safety Exercise

Problem statement. The local newspaper has appeared with the headline “**HEALTH SERVICES GIVE ABSCESSSES**”. The MEC (Health) has instructed the Provincial Communicable Disease Control (CDC) Co-ordinator to form a multi-disciplinary team to find the facts behind this headline. Your team is responsible for the EPI aspects of the investigation.

Instructions

With your small group, prepare a preliminary briefing to the Provincial CDC Co-ordinator on what the possible problems are and how they might be investigated.

Adverse Event Flow Chart



5.5 Sharps are valuable

In many countries disposable syringes, unlike sterilisables, have a value far beyond their nominal cost. There are two main of reasons for this:

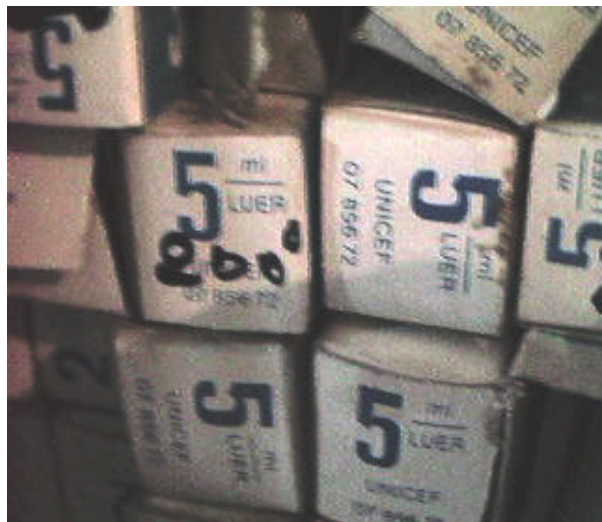
1. Since the advent of AIDS the general public has become more aware of the dangers of dirty injections and they have associated safety with the pre-packed disposable syringe and needle.
2. Disposable syringes are expensive compared to sterilisables and as a result are frequently in short supply in the public sector, and so cannot be obtained free of charge.

In one developing country the price of a disposable syringe from the pharmacy will buy you 1-3 bowls of rice. At an international meeting in 1997 in Central Asia a national representative complained ***“They are expensive, I can buy a loaf of bread for the price of a syringe and needle.”*** By comparison if you go to a supermarket in Western Europe or America you will not find a single item that can be bought for the cost of a syringe and needle.

In many countries items that would be discarded as rubbish in richer countries are recycled. The picture on the right shows oil funnels made from recycled cans. In such an environment the pre-packed product becomes currency. Once this situation exists it is very difficult to ensure that syringes provided to the public sector will not be stolen for sale in the market, or for use in the private sector. In one country the rate of theft from the family planning service is so high that workers have been told not to store all their syringes in one place. Despite this precaution syringes provided for family planning are readily available in the market.



In a country in Southern Africa plans for a measles campaign were nearly derailed in the final days before the campaign was due to start because a lorry carrying all the syringes and needles for a whole region was hijacked and the syringes were stolen.



Chapter 6
describes more
ways to lower
the risks.

There may be a temptation for staff to steal syringes. In the picture on the right a member of the hospital staff is seen passing used syringes to a patient.



In one country in Eastern Europe where the health service is supposed to be free of charge, it has been reported that people reseal the wrappers with an iron so that used syringes can be recycled as new. A woman in that country describing her experience in the labour ward told a BBC reporter that before she was given a pain killer she heard a nurse ask a colleague ***“Is this the one who paid to get a new syringe?”*** We have seen nurses putting new government syringes in their handbags to take home for use in their informal private clinics.

Criminal activity is not limited to theft. A manufacturer in one country paid to have the used syringes returned to the factory.

“...Another alarming problem faced by the people is the re-use of disposable syringes. The discarded syringes, says a hospital staffer, are recollected by the hospital staff from the waste bins and then sold to the scratch dealers from where agents of the manufacturers transport them back to the factories for the purpose to be recycled and repacked for the consumers.”

Frontier Post Pakistan NWFP June 12 1998

Reports of similar recycling have been made in Southern Africa and the Western Pacific.

✗ The fact that a product is in a sealed pack is no guarantee that it is sterile.

One East European country offered its locally manufactured syringes to an international agency. The syringes were tested for sterility and failed all the tests. The following newspaper report shows that this is not an isolated case

“...Another surgeon who wished not to be named, claimed that they carried out culture test of both foreign and local made syringes at Khyber Medical College (KMC) and found that locally manufactured ones were found to be full of bacilli which can bring fever and infectious diseases while the multinational’s were found completely sterilised.

A staff nurse, at Hayat Shaheed Teaching Hospital (HSTH), Peshawar told on condition of anonymity that on several occasions they found syringes with blunt needles, or syringes without needles or with blood stained needles when they open packed syringes brought in by the attendant of the patients.” Frontier Post Pakistan NWFP June 12 1998

5.6 Suitable equipment is not readily available



If incineration equipment is not available, or if the fuel supply for running it fails, then contaminated waste might be burned in an open fire or pit. This type of unmanaged burning can produce dangerous gas emissions and hazardous waste. Unless the plastic bottle full of needles (shown in 4.4) is burnt at temperatures above + 800°C it will produce a bundle of needles that are no longer infected with their original hazardous pathogens. But

they are still sharp and can cause harm, through wounds, infections and uncontrollable organisms such as tetanus spores.

Examples of existing incinerators are shown below. None of them is suitable for burning plastic.



Europe



Asia



Africa

Remedy

For facilities without incinerators see Section 4.5.

Provide sharps containers then separate sharps waste, clinical and general waste to enable operators to fuel their incinerators in a more controlled way to obtain the best burn possible.

Give the incinerator operator recognition that his job is as vital to ensure injection safety as that of the nurse or doctor.

If it is possible consider using commercial incineration companies.

Investigate alternative methods such as sterilising and shredding.

Whatever solution is chosen keep records to show that waste is destroyed.

5.7 Mixed strategies cause confusion

Many countries follow mixed strategies, with one part of the health service using sterilisables while other parts use disposables. There are two dangers when a mixed strategy is adopted.

First, health workers may become confused.

The picture on the right shows the rubbish from a clinic that in theory used plastic sterilisables for immunisation, and disposables for other services. In the past they had been supplied with glass syringes so when a new supply of plastic (sterilisable) syringes arrived - with no explanation - the worker assumed that all plastic syringes were disposable and threw away the EPI sterilisables (lower



pointer) together with the curative disposables (upper pointer).

Naturally injection equipment was in short supply; in the same clinic, the worker was boiling a mixed pot of disposables and plastic sterilisables to eke out enough syringes and needles to cover the workload. What was management's role here?

Second, workers may perceive one technology as being more important than another. In one African country the curative services' injections (using disposables) were visibly less safe than the immunisation injections (using sterilisables). Both services are provided in the same clinic by the same workers, who alternate between the MCH clinic and the treatment room.

When asked why they followed different practices for immunisation injections from those that they followed in the treatment room they replied,

"We are supervised for EPI and we have to sterilise the syringes so we take more care. Nobody worries about the others because we can just throw them away"

Emphasise to staff the importance of following the same standards for all parenteral procedures.

Make sure that staff understand the practices they should adopt for each technology.

5.8 Health workers allow standards to fall

Most health workers will try their hardest to give care which is of a high standard. Often, people who become health professionals have some ideals about their work, wanting to care for and help others. This becomes a kind of personal moral obligation to carry out their roles in a way which is of benefit to those they serve. In some countries, this moral obligation is also a legal one (the UK is one example) and anyone who is caring for another person has a legal duty to do so to a high standard, and in a way which does the person no harm. This is known as their **duty of care**.

There are many reasons why health workers become careless. They may be demoralised because they have few resources, or because they haven't been paid for a while. Or they may feel isolated in a rural area, unsupported by the community they work with. The results of carelessness can, however, be lethal for patients.

It is a worthwhile investment to spend time working with staff to agree standards of care in injection practices. (See Section 6.3 on supervision.) It means that staff are clear about what is expected of them – what is their duty of care – with patients. Both supervisors and staff can examine the available resources, and the efficiency of systems for the delivery and maintenance of stock. Staff can be encouraged to identify their own learning needs, and supervisors to consider ways of meeting those needs. (See Section 6.2 on education.)

However, standards are only useful as long as they measure health workers' performance, so once they are agreed, there should be a regular review of how well health workers are meeting the standards. If there are too many lapses in high standards of care, then it is time to consider what the causes may be, and what can be done about them. This review process can be part of a supervisor's role, and is educational as well as managerial, so a supervisor helps health workers improve their practice through assisting them to identify and solve the problems which cause standards of care to fall.

5.9 Injections in the private sector

Frequently the safety of injections in the private clinics is totally unsafe.



The picture of the left was taken in a private doctor's clinic in Southern Africa; it shows several vials with needles piercing the septum and two syringes amongst the vials of assorted drugs.

The photo on the right was taken this year in a private pharmacy in Asia. This was the only syringe in use; it was left standing in a beaker of water all day and used on any patient who came for an injection. The doctor (a qualified MD) who had a clinic in the back of the pharmacy was asked why he did not tell the pharmacist to use a new syringe each time. He replied,



"I write the prescription, it's his job to give the injection"



This is the clinic of a private pharmacist in Eastern Africa. He has several syringes, all in use and all lying loose on the table mixed up with drugs and wrappers. The likelihood of him getting needle stick before injecting a patient is high, and given the conditions he is probably infected with bloodborne pathogens. There is also a very strong probability that the syringes are contaminated.

Remedy

In some countries there is a system for registering drug vendors as well as pharmacists. They are required to meet basic standards for both prescribing and giving injections.

Such health care providers must be trained and regulated.

5.10 Records


An essential part of injection safety is maintaining accurate and clear records of activity. In most health services it is a requirement to maintain a treatment register. However this is not a user-friendly document and finding the number of injections given in a particular period is often very tedious. The injection and dressing register is one way to make it easier to keep a tally on numbers of injections given in a specified period.

The example on the right comes from Africa and clearly shows, on a daily basis, the number of injections and dressings that have been carried out. With such a record it becomes possible to compare the injections administered with quantities of injectables used.

Date	Injection	Dressing
19-6-96	II	II
20-6-96	III	II
21-6-96	II	II
22-6-96	II	II
23-6-96	II	II
24-6-96	II	II
25-6-96	II	II
26-6-96	II	II
27-6-96	II	II
28-6-96	II	II
29-6-96	II	II
30-6-96	II	II
1-7-96	II	II

Date	Injection
19-6-96	II
20-6-96	III
21-6-96	III
22-6-96	II

Unless there is transparency in record keeping, misappropriation of syringes becomes very easy.

 The picture on the right shows used syringes seen at clinic in Asia; they were given by the family planning service to the curative care service, which wanted the FP staff to hide the fact that some of their syringes had 'gone missing'. Accurate records, witnessed by more than one person, would make such activities easier to spot and thus easier to prevent.

If commercial waste disposal companies are contracted to destroy sharps waste the originator of that waste must be able to show that their duty of care has been passed to another party. This means that the health worker must have a record that shows when the waste was handed over for destruction and another which confirms that destruction has taken place.



The result of the problems described in this chapter is a major **potential** health **hazard** that must be addressed; it is possible to **reduce** the risks.

6 Ways to lower the risks

What can be done to minimise the risks described in the preceding chapters?

It is possible to reduce the risks, but the management and handling of syringes and other medical sharps requires commitment, attention and effort - before, during and after use. Technology and money are necessary inputs, but of themselves do not guarantee safety. Support systems, training and effort are the basis for achieving results and reducing the risks.

Ways to lower the risks include:-

- reducing the total number of injections
- making sure every injection is safe to client, health worker and third parties
- getting rid of the waste safely

These measures for reducing the risks can be applied to each area of your health services:

- maternal and child health
- family planning
- immunisation
- curative care
- diagnostic services
- blood collection
- dentistry

Under some circumstances it may also be relevant to apply these measures to the veterinary services, which also use injection equipment. They also sell disposable syringes to the general public. In one Asian country a veterinary worker reported that his most popular size of syringe was 2ml and he sold several dozen each week, mostly to people who found his clinic more convenient than the village pharmacy.



Remedy

The total number of injections can be reduced by:

- reducing the number of unnecessary injections
- changing prescribing habits from injections to oral preparations
- convincing the public of the validity of alternative treatments
- keeping policies and guidelines up to date
- investing more in knowledge and skills of prescribers and suppliers

Making sure every injection is safe will involve:

- investing in staff skills to assure the quality of sterile technique
- supportive supervision and motivation to achieve a higher level of duty of care
- allocating sufficient budget for purchasing equipment
- allocating sufficient budget for consumables
- procuring the right quantities of injection supplies
- ensuring stocks never run out: good distribution and stock management

Getting rid of the waste safely will involve:

- investing in staff skills for clinical staff, cleaners and incinerator operators
- supportive supervision and motivation to follow guidelines
- confirming that disposal is safe and environmentally sound
- allocating sufficient budget to buy disposal and destruction equipment
- allocating sufficient budget for consumables used for disposal and destruction (sharps containers, fuel, transport)

The following matrix illustrates the potential opportunities for reducing the risks from unsafe parenteral procedures. (The bigger the 'eye' the bigger the opportunity.) The left hand side shows service elements that can contribute to reducing risk by changing behaviour, including changes in prescribing habits and clients' expectations, and practice development. Changes in management and in financial allocations also offer opportunities for improving safety of injections and other parenteral procedures.

Potential opportunities for lowering risks¹

		MCH	Family planning	Immunisation	Curative	Diagnostic	Blood collection	Dentistry
Illustrative number of parenteral procedures per 1,000 population per year		40	110	200	1,870	375	150	225
Service Elements								
Change prescribing habits and behaviour, + Social mobilisation	Reducing unnecessary injections							
	Changing to oral preparations							
	Convincing the public not to choose parenteral procedures							
Practice development and behavioural change	Updating policies and guidelines							
	Investing in clinical skills							
	Investing in pharmaceutical skills							
	Investing in ancillary staff skills							
	Improving quality of sterile technique							
	Supportive supervision for duty of care							
Management	Allocating sufficient investment budget							
	Allocating sufficient recurrent budget							
	Effective distribution and stock mgt.							
	Confirming that disposal is safe and environmentally acceptable							

1. The matrix is based on data from selected countries and is for illustrative purposes only.

= moderate opportunity

= strong opportunity

6.1 Changing prescribing habits

Some of the changes which might have to be made to improve practice and safety centre on changing prescribing habits. In order to reduce the number of injections and change to oral preparations health workers will have to be persuaded that these changes are necessary.

There is now considerable evidence from research that it is extremely difficult to persuade health workers to change their clinical practice (Haines and Donald, 1998).

Research also shows that some management and educational strategies are more likely than others to lead to successful changes. These may be new techniques for your country, but if you are considering investing in training and management for safe injections, then it is worthwhile considering these options, which have a better chance of success.

- Finding out what current practice is by carrying out an assessment of what practitioners do is moderately effective at changing their practice – if they are given feedback about what is found.
- If reminders are sent after an audit, emphasising the new standards to be followed, then this will make the audit much more effective as an intervention for change.
- Educational meetings which allow the participants to take an active learning role are consistently effective at changing practice.
- Using local opinion leaders to pass the message about injection safety will be effective, especially if it is part of a broader strategy.
- Any two or more of the interventions described above will have more effect than one alone.
- **It is known that guidelines alone and lectures have little or no effect on practice.**

6.2 Investing in practice development for staff

Helping staff to change their practice is a cost-effective investment, provided that the interventions are known to work. The previous section outlines some interventions that have produced positive results.

To be skilful and effective practitioners, health workers need knowledge, skills and attitudes on which to base their practice. Some of this comes from role modelling, and some from basic education, but much of it comes from continuing education, which ideally should be life-long.

- Education need not be expensive to be effective. Neither need it take practitioners away from their jobs. In fact, there is growing evidence that practitioners who learn **while** working use their knowledge more in practice.

This is logical and sensible, but it is surprising how few educational initiatives are based in practice settings. Placing a health worker who is respected and has high standards of practice in a health centre where improvements are needed can help health workers identify the need for change, and model their practice on good practice.

- Small group discussions carried out in health centres, with staff from either one health centre or a few local sites, can help participants to solve their problems around safe injection practice. If the discussion is facilitated so that problems are identified and then staff brainstorm around solutions, a creative atmosphere is established, where health workers can learn actively how to improve their practice situations.
- Try regular weekly lunchtime discussions rather than infrequent long courses.
- Ensure that basic medical and nursing education gives students a chance to practice their injection skills, and to discuss the components of a safe injection policy. This is one way to ensure sustainable changes.
- Setting up a system where health workers review their practice with each other is another effective method of helping them improve what they do. The review need not be formal, but it should be regular, friendly and supportive. Health workers can describe their practice situations to each other, or can even watch each other at work. Then one can help the other to discuss issues which arose. For example, one might ask: ***“I noticed that you had to throw away some of the injection equipment into an ordinary cardboard box. Last week you had a special container. What has happened to cause this change in practice?”*** This is a gentle question, which will help the person questioned to consider the root of a problem, and by doing so, consider solutions.

6.3 Supportive supervision

At one time supervision was thought of as a management process, like checking up on practice. Now it is known that the process of supervision has great potential in bringing about positive change, especially if it is supportive, rather than punitive.

Some ideas for ways in which supervision can be used have already been discussed in this document. Consider the following:

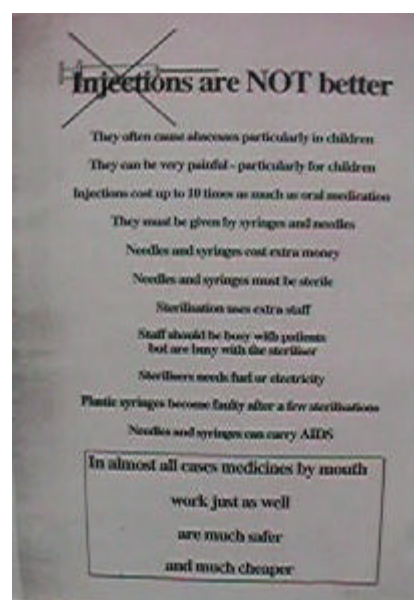
- Do supervisors in your country have some learning opportunities to help them become effective supervisors? Sometimes people are promoted because they have been in service for a long time, but there are particular skills in being a good supervisor, and it is valuable to invest in these.
- People learn from their mistakes. It is unhelpful to have a culture of blame in an organisation, so that people are afraid to acknowledge that they have made mistakes. One of the greatest motivations for change is the realisation that

change is necessary and that it will be of benefit. What is the culture in your organisation?

- Supervisors can become facilitators of small group teaching sessions, which offer an excellent way of improving practice. Some examples are given in Section 6.2 above.
- Make sure that supervisors are involved in setting standards of practice with their co-workers, and in monitoring them. If you are not sure how to set up a quality assurance system, then seek for help. Places you might look are The British Council, WHO Human Resource Development Division, Geneva, through your country office, local university management schools if you have them, and nursing schools too, where much work has been done on quality and standards, and the World Wide Web, if you have access to it.

6.4 Social mobilisation

Persuading the public to ask for safe injections, to refuse unsafe injections and to seek oral instead of injection treatments is no easy task. Seek help from units in your health service who specialise in social mobilisation. There are many ways of getting publicity: through the media, through health education drives, through schools and child to child initiatives. Which way is right for your country will depend on many factors.



6.5 Operations management

A wide range of health service management activities is involved in supporting safe injection practices. Procurement decisions on choice of equipment and supplies and quantities of each are crucial, as is the management and distribution of the stock. New activities may have to be planned and developed, such as training and supervising incinerator operators, and auditing disposal and destruction of the clinical waste described in previous chapters. The staff involved are not only those providing services but also a wide range of ancillary staff who perhaps are not usually considered a priority for on-the-job training and supportive supervision.

6.6 Funding

Two of the elements listed in the matrix refer specifically to budget allocations. These may be for investing in medical equipment or incinerators, or wider investment in the infrastructure to facilitate the safe destruction of the health

services' waste products. Allocations are clearly needed for recurrent supplies. Other elements in the matrix also refer to investment in developing skills; relatively small amounts of funding can produce significant improvements if spent on effective interventions (see Sections 6.1 and 6.2). Supervisors need resources, especially transport, to support their people on the job, and fulfil their expected role. Financial shortfalls or late arrival of funds are often cited as factors contributing to lapses in quality of services, such as lack of supervisory support or stock outs of supplies. Financial constraints are more subtle than whether the amount available is enough to buy the necessary goods.

Think long term to find the best approach for the local situation:

- how to improve staff understanding and competence
- how to create plans that are financially viable
- how to run operational support systems effectively
 - procurement, stock management, distribution, destruction
- how to build confidence amongst workers and clients that your health systems are safe

The situation in your country is specific, and needs careful consideration.

Start now but take enough time to choose the right solution.

7 Consider the circumstances

In order to minimise risks, you must take into account the circumstances that affect the safe handling of syringes and sharps in your health services, and your ability to make improvements. How safe are your health services? In the spectrum of possibilities for minimising the risks, where are the relative strengths and the best opportunities in your circumstances? There are three fundamental components of your health systems - behaviour, management and finance - that will affect how those technologies are used in practice, and whether the systems for managing and controlling medical sharps are safe. Many aspects of these three components have been illustrated and discussed in earlier chapters of this document. You will need to consider the three elements - behaviour, management, finance - in assessing your circumstances, before choosing the best solution.

7.1 Behaviour

Attitudes and perceptions vary between different communities and cultures.

- **Attitudes to disposable devices in a “non-throw-away” society**
Some people find disposing of almost new syringes very difficult to accept, and so tend to re-use syringes. (See Case Study 1 in Chapter 9.)
- **Staff compliance with duty of care**
Some health workers are more diligent than others about the correct use and disposal of syringes. The importance of proper sterilisation and of safe disposal may not be fully appreciated.
- **Danger of theft**
Unused syringes can be stolen. The risk is directly related to the local value (purchasing power) of the commodity, and to demand from potential patients.
- **Pressure to treat clients**
Health workers may fail to understand the full implications of using contaminated equipment, and take risks, rather than announcing to the waiting patients that they have no more sterile injection equipment.
- **Expectation by clients to receive injections**
Some people expect to receive an injection every time they need treatment
- **Medical practice and beliefs regarding treatments**
Paediatric opinion in an East European country is that sick children suffer from “digestive insufficiency” so that they cannot absorb drugs in oral preparations. The medical community in that country also regards mothers as generally incompetent to administer syrups to sick children, who therefore receive treatments by injection. Studies in that country show that infants (under-1s) living with their families received an average of one injection every 2-3 weeks, and infants in institutions received one injection every 3 days.

The effects of the last three points are illustrated in Tables 1 and 2. In order to compare places with similar levels of resources and similar health status we have chosen seven countries in Europe. (The choice was determined by those with data on injectables both inside and outside hospital.) All the countries in Table 1 have

- a mortality rate for under-5s of less than 10 per 1000 live births;
- GNP per capita of at least \$18,000 per year.

Yet the average number of injectables per person per year (Column b) varies by a factor of six; compare Italy with the Netherlands. These variations are caused not by differences in wealth or morbidity but by differences in medical practitioners' choices of treatment, and in clients' preferences and expectations concerning the type of treatment they consider appropriate.

Table 1 Injectables per capita per year in seven European countries

Country	a Population (millions)	b Injectables/ capita/year	Outside hospital		Inside hospital	
			c Inj/cap/yr	d % of total	e Inj/cap/yr	f % of total
Italy	58.3	12.7	7.6	60%	5.1	40%
France	58.1	8.9	3.7	41%	5.2	59%
Austria	7.9	8.0	2.8	35%	5.2	65%
Germany	81.3	6.7	2.7	40%	4.0	60%
Finland	5.1	3.6	0.7	20%	2.9	80%
UK	58.3	3.5	0.5	14%	3.0	86%
Netherlands	15.5	2.3	0.6	26%	1.7	74%

Sources: Population data: UNICEF. Estimates of injectables: Romacker (1998).

In six of these seven countries the majority of injectables are administered in hospital (see Column f). The exception is Italy, where 60% of injectables are given outside hospital. The three countries with the lowest rates (Finland, UK and the Netherlands) administer significantly fewer injectables per capita than the rest, and dramatically fewer are administered outside the hospital setting. This is true whether comparing absolute numbers of injectables per capita or the percentage of all injectables given outside the hospital setting.

Table 1 shows that the number of injections per capita varies enormously between countries, and the variation is not explained by differences in health status or GNP. These findings illustrate the potential for reducing the number of parenteral procedures by changing the behaviour of both practitioners and their clients. The way in which this might be done is specific to each health system and its culture.

Table 2 gives further evidence of variations regarding treatment; this table shows that the equipment used to administer injections does not follow a uniform profile. In some countries clinicians are using syringes of smaller size with the result that their overall costs (equipment, freight, storage, distribution, disposal, destruction) are lower.

Table 2 Profile of syringe sizes used in three countries

Syringe size	South Africa ^a	Romania ^b	Eritrea ^c
1 ml	11%	0%	3%
2 ml	44%	26%	18%
5 ml	28%	51%	59%
10 ml	16%	18%	20%
20 ml	1%	5%	0%
Total	100%	100%	100%

Sources: (a) Battersby (1995); (b) Battersby (1993); (c) Battersby (1996).

If all of the countries shown in Table 2 had the same profile of syringe sizes used as South Africa, the cost of syringes alone (ex works) would be at least 10% to 15% lower. Further savings accrue from lower freight costs, smaller storage volumes, and less volume of material to be disposed of and destroyed.

At the moment of administering an injection the choice of syringe size may be determined principally by habit and by what is available. Thus the opportunities for change include not only practice development but also procurement decisions that are made far from the point of service delivery.

7.2 Management

Effective management is required both to design feasible operational systems and to make them run as designed.

- **Technical capacity**

Skills and experience are needed to update policies, and to design and implement appropriate systems, including procurement, stock control and logistics. (See Case Study 4 in Chapter 9.) Standards and regulations are needed for both the public sector and for non-governmental and private providers. What are the systems for monitoring compliance? Are there standards covering the necessity of continuing education or in-service training - for both the public and the private health sector? (See Section 5.9.)

- **Human resources**

People are the bedrock of any health system. Human resources are needed to train, supervise and support staff, to manage operations effectively, and to monitor compliance. Where a significant proportion of injectables are administered outside public facilities, are there enough staff for monitoring private sector compliance with safety standards?

- **Security of used syringes**

Used syringes can be recycled, even repackaged (see Section 5.4). Are there audit systems for managing and monitoring contaminated waste?

7.3 Finance

The sources of funding must make a commitment to provide essential supplies and equipment.

- **Capital Investment**

Investment will be needed in one or more of the following:

- injection equipment (capacity building, transferring Good Manufacturing Practice skills - for example via the European Union's know-how fund)
- sterilisation equipment
- equipment for waste disposal and incineration (transfer of technology provides an opportunity for investment)
- warehousing
- vehicles

- **Infrastructure**

The existing physical infrastructure may offer opportunities or constraints for reducing risks and improving safety:

- disposal and destruction systems for contaminated sharps
- transport systems and distribution networks for resupply and for carrying used syringes to the nearest incinerator
- communications

- **Recurrent costs**

Recurrent costs, or operating costs, include:

- syringes and other sharps - some cost less than others; some can only be used once; the number of times sterilisable items can be reused varies
- fuel for running sterilisers and incinerators
- safety boxes for disposal of medical sharps
- supervision and in-service updating of skills
- transport costs
- contracts for the destruction of contaminated waste

The profile of a country's financial commitment to safety of injections and other parenteral procedures depends on the behavioural factors described above and illustrated in Tables 1 and 2. It also depends on the efficiency and effectiveness of operations management.

To illustrate some of the financial implications of strategic choices, we have estimated the costs of using sterilisable technologies and disposable technologies. The mix of injection equipment (proportions of syringes and needles of each size) is based on programme guidelines and on data collected from three countries. Details of the assumptions are given in Annex 2. The cost for one million parenteral procedures under these assumptions is shown in Table 3, comparing sterilisable technologies with disposable technologies (standard disposables).

The illustrated costs indicate the comparative level of financing that must be committed year after year to ensure sufficient supplies for safe injections. Other

costs that do not appear in Table 3 include staff time, fuel for heating sterilisers and for incinerating waste, and the cost of storing and distributing supplies. The two strategies also entail different levels of effort for ensuring correct behaviour, effective management and continuing financial allocations, and these aspects are highlighted in Section 7.4 below.

Table 3 Illustration of costs for supplies and equipment, per million parenteral procedures for two strategies: sterilisables and standard disposables

Item	Sterilisables/million PPs ^a		Disposables/ million PPs ^a
	33% of uselife ^b	100% of uselife ^b	
Needles, syringes and lancets	\$8,275	\$2,758	\$63,933
Equipment for steam sterilisation ^c	\$6,701	\$2,581	\$0
Sharps containers for disposal ^d	\$184	\$61	\$11,674
Total	\$15,160	\$5,402	\$75,607

a Costs per million parenteral procedures (including lancets).

b See Annex 2 for assumptions

c Includes steam sterilisers, stoves, forceps, TST spots, hard water pads, and spare parts (used at a rate from recorded experience). The first three items have been amortised over a uselife of 10 years with a discount rate of 10%.

d These costs do not include incinerating or destroying the sharps containers when they have been filled with contaminated waste.

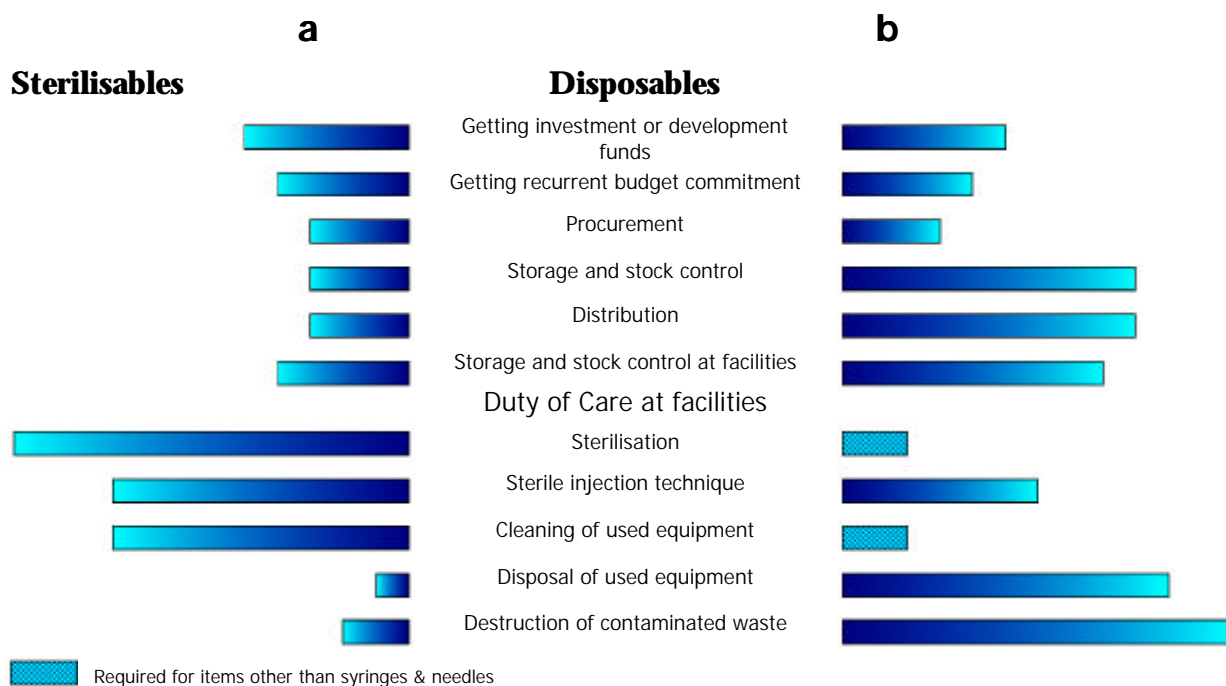
It must be emphasized that the figure of \$0 for sterilisation equipment in the scenario using disposable equipment is inconsistent with a holistic approach to safe practice. No health service runs entirely on disposable items, and every clinic where wounds are dressed or speculums are used must be able to sterilise equipment. No one would suggest discarding a pair of scissors or forceps after one use, and suitable equipment must be procured and used for sterilising such items.

Annex 2 contains further examination of comparative costs using sensitivity analysis that varies the assumptions underlying the estimates.

The model used for illustrating these costs contains dozens of variable factors which can affect the conclusion, and which change over time. For example the price of the 0.5ml autodestruct syringes has fallen to 65% of its price five years ago, and prices of sterilisable syringes have fallen even further (to 49% of 1992 prices). We do not have robust information for the other costs mentioned above - especially for destruction of waste. There are problems with translating effort and commitment into monetary terms, yet these essential inputs must be recognised when assessing the feasibility and sustainability of options for improving safety. The next section takes a visual approach to representing these non-monetary components.

7.4 An illustration of the comparative levels of effort and attention

The following chart identifies the various components of health service delivery (down the centre), and compares the amount of effort that must be devoted to each component in (a) a system using sterilisable injection equipment and other medical sharps with (b) the effort in a system using disposable syringes and sharps. The longer the bar, the greater effort is required to implement that component.



7.5 What are your options?

Considering the circumstances of your health services, what are the options

- for changing behaviour?
- for strengthening management?
- for allocating financial resources?

Identify **key** areas where improvement and change can be achieved.

How do these options fit with the features of the available technologies?

There are two basic choices of technology for giving injections: sterilisables and single-use disposables. Each technology is a part of a system. If part of the system is missing, the technology cannot be used safely.

"... you can't get all excited about a product and think it will solve [the problem of needle stick injuries]. If it was so simple we would have already figured it out."

Murray Cohen, former CDC chief of medical device evaluations,
quoted in The Washington Post, August 1998.

The technical options now available are presented in Annex 1, with their advantages and disadvantages.

8 Your next move

Faced with problems of the type described in this document, some people decide that the whole issue of safety in their health services is too complex, and the current situation is best left well alone. Trying to tackle the problems might call attention to them. Doing nothing is an option, but at best it will result in no improvement in health status. At worst, the health of the population will deteriorate and loss of trained staff due to long term illness and fatalities will accelerate.

The next step should be to set up a Safe Medical Sharps Task Force with the long term objective of improving the safety of injections and use of needles and other sharps, and ensuring safe disposal of contaminated waste.

The task force must be at a senior level, and its terms of reference should include an impartial consideration of the varying needs of the different health care departments (maternal and child health, family planning, immunisation, curative care, diagnostic services, blood collection, dentistry).

Guidelines for the Task Force

1. Set the Terms of Reference
2. Assess the current situation and key factors affecting
 - government departments
 - health management
 - health workers in the formal and the informal health sectorwith reference to behavioural, management and financial issues
3. Identify key problems, policy issues and operational implications
4. Analyse which injection systems seem to be most suitable for different parts of your health care operation, and prepare a plan for minimising risk from unsafe needles and sharps
5. Define short term actions in detail
6. Outline long term actions

This assessment is the foundation for a safe injection policy for your country. Therefore it is vital that the assessment is as accurate as it can possibly be. This means there must be a systematic data collection process using survey instruments designed for your circumstances. The assessment team should include members with clinical/nursing skills and operations management expertise. The assessment must include observing practice, and talking with health staff, ancillary workers and members of the community at the point of service delivery. Interviewing supervisors and support staff (for example storekeepers, procurement staff and finance officers) is an essential part of the assessment. During interviews time must be allowed for staff to give the team feedback. Time will also be needed for the team to reflect on their findings before finalising their conclusions. The assessment is an iterative process; do not expect to complete it in one step.

The following two examples show how, in different parts of the world, progress is being made to address the issue of injection safety.

In 1993 the Western Pacific region (WPR) of WHO embarked on a programme to improve the safety of injections for immunisation throughout the region. Eight of the 36 countries in the region have been prioritised for action, and five of these have produced national plans of action (WPR/EPI, 1998).

These national plans cover:

- national policy on the safety of injections, including equipment of choice;
- the establishment of standard acceptable quantities of sterilisation and injection equipment at health facility level (either disposable or re-sterilisable);
- the adoption of a minimum replacement period for both sterilization equipment and re-sterilizable injection equipment;
- appropriate training for staff involved in the EPI at all levels;
- the calculation and costing of annual national requirements on the basis of the above standards.

This initiative focuses on immunisation but it has great relevance for all aspects of health services in the region's countries. The report on activities concludes:

- the development of national plans of action to improve injection safety has had mixed success in terms of implementation and needs further follow up
- the use of disposables in most countries is becoming more widespread and in the long term it will not be possible to control their continued use for immunisation
- the focus should now be on the introduction of methods of safe disposal (safety boxes) and safe destruction; there remains a need for a reliable, cheap, effective incinerator for use at province or district level
- injection safety in campaigns has been improving through better planning and increased use of autodestructs and safety boxes, but a major gap remains in the development of plans for the collection and destruction of used equipment
- strategies to improve the safety of injections will vary depending upon the situation of individual countries in WPR.

Actions for consideration:

- **Progress in implementing national plans to improve the safety of EPI sterilization and injections practices should continue to be evaluated.**
- **The use of safe disposal boxes should be strongly promoted for all EPI activities where disposables (including autodestructs) are used.**
- **Further efforts should be made to identify and field trial appropriate incinerators.**
- **Plans for all campaigns using injectables must include clear consideration of injection safety, including calculations of requirements, the use of safety boxes where appropriate, and plans for the destruction of used equipment.**
- **Operations on injection safety should reflect the situation of individual countries in order to achieve maximum benefit.**

Efforts in the WPR represent a substantial achievement, and they should provide a guide for the rest of the region's health services.

In Zambia a consensus meeting was held in 1998 on updating immunisation policy within the context of health sector reform. Proposals from the meeting were presented to the MoH and included the following:

3 Policy on safety of immunization injections

The WHO Expanded Programme on Immunization defines a safe injection as one that:-

- does no harm to the recipient,
- does not expose the health worker to avoidable risk,
- and does not result in waste that puts others at risk.

Immunization injections are to be administered using equipment sterilized under pressure in steam sterilizers. Needles and syringes are to be replaced as soon as they reach the end of their useful life.

Disposable injection equipment (conventional disposables or autodestruct/solo shot devices) may only be used where proper disposal facilities are available, complying with the third element of the definition of a safe injection.

If sterile injection equipment is not available (e.g. the TST (time/steam/temperature) spots show that sterilization equipment is not reaching the required standards, or there is no equipment in stock) then immunizations should not be given.

Recommendations for guidelines on adverse events following any parenteral procedure

Guidelines for reporting adverse events following any parenteral procedure (AEFAPP) should include a dual reporting channel: from the patient or community (NHC) to both the Health Centre Advisory Committee and the District Health Board.

Guidelines for investigating AEFAPP should be developed by CBoH's Directorate of Monitoring and Evaluation in conjunction with the epidemic surveillance system. WHO's document, *Surveillance of adverse events following immunization* (1997 revised edition) provides a starting point.

Quality assurance standards for safety of injections and other parenteral procedures (including laboratory procedures) should be developed.

Procedures should be developed for establishing an audit trail for disposed sharps waste. (Feilden, 1998)

Always remember that the key defining issue is respect for duty of care - "First, do no harm"

9 Case studies

Imagine that you are part of the Task Force set up to improve the safety of parenteral procedures in your country. During an assessment of injection practices you encounter the following cases. (They are all based on real incidents; you may have seen some of them in the ***Vital to health?*** brochure.) Discuss with some colleagues - or just consider by yourself - what questions you would like to ask to find out how the problems can be put right. What would be your line of enquiry?

The first three cases are followed by commentaries indicating the analytical processes that the Task Force could take when assessing the safety of injections and other medical sharps. The remaining commentaries are briefer, indicating some approaches for understanding the situations found during field visits. All the commentaries are illustrative, not definitive.

You may wish to pause before reading the commentaries, and consider what approach you might have taken if you had been there. Here are some pointers:

- Identify all the factors contributing to the problem.
These factors may be outside the immediate domain of the health worker and the facility itself.
- What can you solve now?
- What can be solved with an investment of further effort?
- What do you think is beyond your control to solve, and why?
- What would you do next?

CASE STUDY 1

The nurse knows how to give injections, and does her work without causing her patients undue discomfort. She believes that the syringes supplied to her are expensive; they are imported, and come in a packet.

She lives in a frugal society, which recently won a war by capturing the enemy's vehicles and supplies, and saving everything that might have a future use.

On the day of our visit we noticed that she used the same syringe and needle on two brothers.

We asked the nurse why she had used the same equipment on two patients. She explained that she thought the risk would be lower within the family, and she was worried that the supply of sterile syringes might run out.

We asked to see the stock of syringes, and counted them.

The health centre store contained 5,600 unused disposable syringes and 8,800 needles. Using the treatment book and monthly reports, she helped us to work out the expected number of injections per month. Together we worked out that the store held enough syringes for 9 months of service delivery at the current workload, and enough needles for more than a year's work.

More data were collected from the national level.

At first we thought that her fear of shortages was due to her experiences during the war. But the macro-level analysis for her country showed that the number of injectables imported per year was double the number of disposable syringes imported.

Commentary

If you were on the assessment team, what would you like to ask the nurse now?

It is important to know **why** people behave as they do. Most people have what they consider to be good reason for their behaviour. Why does this nurse believe that she will run out of syringes? It is true that she lives in a society where saving and recycling things is important, but it may be that she has run out of syringes before, and she is now taking preventive action.

How could you check this possibility? First by talking with the nurse:

- Have you ever run out of syringes? of needles?
- When was the last time?
- What caused the problem? Why did it happen?
- For how long did you have no stock?
- What did you do?
- What did your superiors do?

How was the problem solved?
How could it be avoided in the future?

In retrospect the nurse had every good reason to worry that her supply of sterile injection equipment will run short. Paradoxically, her hoarding of syringes was contributing to the problem of ensuring regular resupply to others.

On the surface, it seems that the nurse perceives disease transmission to be a lesser problem than running out of sterile syringes. So another approach to understanding the nurse's behaviour is to find out what she knows about disease transmission and risks of infection.

When was she trained in the principles of cross infection?
Was it recently, or many years ago?
Has she had any in-service updating of skills?
When was this topic last addressed?
Does the supervisor discuss day-to-day practice with her?
Has she ever seen a case of hepatitis B? What are the signs and symptoms?
Does she know that the majority of children infected with hepatitis B virus show no symptoms whatsoever?
Does she know that if she changes the needle but uses the same syringe, the injection is not safe?

She may simply not have the necessary knowledge to practice safely.

Who else would you like to ask about this problem that you have encountered?

You could talk to the next level up - the supervisor, the person in charge of stocks and distribution of supplies, and ask them a similar set of questions.

You would probably want to talk to the procurement officers - what do they know about the risks and the burden of disease that the shortage of sterile injection equipment is inflicting on the population? Why is it that enough equipment is not ordered? What are their reasons for this situation?

How about the financial planners? Do they understand the importance of injection safety and the equipment and supplies needed for this? Is there any feedback mechanism to ensure that the financial planners know the effects of their decisions?

What about the decision makers and politicians?

Taking action

How will you and other members of the Task Force decide whether priority should be given to improving clinical knowledge and behaviour, or to publicising the effects of spreading pathogens through unsafe procedures? Or should the priority be to ensure that funding allocations and procurement decisions are based on a full appreciation of the consequences and their attendant risks?

CASE STUDY 2

The national strategy for controlling malaria is based on active surveillance, which requires blood samples collected from fever cases in the community.

The health worker plays his role in monitoring malaria, taking thick and thin blood smears from people with fever. He has a box to hold the slides, which he takes to the supervisor's monthly meeting at headquarters. During malaria season the lab is busy and gives him the results in 6 to 8 weeks.

His manual says that lancets are to be used as finger prickers. They are to be placed in a stoppered glass jar of surgical spirit to disinfect them between patients. Unfortunately the jar broke months ago. The rule is that staff must pay for breakages.

This health centre was built as a self-help scheme, and the health worker is a government employee. For the opening ceremony some equipment and drugs were sent, but he has never received any more supplies. His lancet is no longer sharp, and people began refusing to allow him to prick their fingers. He has obtained three hypodermic needles from his colleague 5km away, who has a steam steriliser. It was issued during a national campaign several years ago, before this self-help building was established. The needles are very sharp and people do not complain when he takes the blood for the smears.

Not many people come to the health centre; they prefer to go straight to the market stall selling chloroquine, aspirin and other essentials. So to keep his monthly reporting targets within sight, he works house-to-house, finding a dozen or more fever cases in one day of outreach visiting.

Commentary

Despite the known delays in analysing smears collected by health workers, the latest strategy is to expand the present monitoring system by training volunteers to collect blood smears from fever cases in their own communities. If the malaria control specialists took a holistic approach, recognising both the risks of transmitting bloodborne pathogens and the realities of supply shortages, then less dangerous strategies could be explored. For example if specialised surveillance teams were equipped to collect blood smears safely from a scientific sample, they could feed back the results promptly. What would be the costs and benefits of this radical departure from existing practice? Could it be funded as research (rather than depending on local health services to cover the costs)?

Within the same country there are donor-assisted projects to interrupt the transmission of HIV amongst truck drivers. The manual for malaria workers is out of date; the instructions to disinfect lancets need to be replaced with sterilisation procedures that comply with new safety standards.

The whole arrangement for providing equipment and supplies is not working. The opening of this facility may have helped to fulfil a target, but the effect of posting unsupported health workers may be that they spread more serious diseases than they are trained or equipped to treat. How can this be explained to the self help group who worked so hard to build themselves a health centre? With whom do they communicate in the health system?

What can be done now? Perhaps the priority is to agree an approach that will most effectively minimise the risks of disease transmission. The fact that malaria itself can be transmitted by contaminated needles may help in the discussions.

CASE STUDY 3

The assessment team was puzzled. They had prepared their survey formats based on the programme's policies and guidelines, which stated that sterilisable injection equipment is to be used, with detailed instructions for the sterilisation procedure.

When the team visited the selected facilities they found that the urban health centres were all using standard disposable syringes. They asked the staff on duty about it. One nurse replied:

"The packaged syringes are easier for us to use.

Were you here at 8 o'clock? Then you may have seen the people waiting.

With the old syringes we couldn't start giving injections until the steriliser had cooled down. If someone had a transport problem or the electricity was out or any type of delay like that, the syringes would not be ready and everyone started to be less patient.

Also using the forceps it takes more time to assemble the syringe.

With these wrapped syringes, one nurse can finish the queue of patients before tea break, and there is no cleaning and sterilising to do afterwards.

At first we didn't know what to do with the used ones. Then we asked the cleaners to save empty plastic containers. We put the used needles in a plastic bottle and the syringes in a cardboard box, the same as the one they come in. Then the cleaner takes them away for burning.

The people are pleased that their injections come from a syringe in a packet.

Occasionally we run short - sometimes it is needles, sometimes syringes.

When this happens we ask patients to buy their own - there is a trader across the street who sells the same brand of syringes as ours.

I think most of them can afford it - it costs the same as a loaf of bread."

CASE STUDY 3 continued

The team watched the rest of the clinic session, then checked the stock records and the activity reports, and asked the cleaner to show them what he did with the syringes and the plastic bottles of needles. Meanwhile they asked the driver to go across the street and do some market research with the trader.

Commentary

The health system has not supplied the “disposal” part of the technology. In fact this facility is equipped with an incinerator (for destruction of waste) but it is out of use (*why?*) because the diesel required to operate it has run out (*why?*) because the imprest (cash float) has not been topped up (*why?*) because the petty cash accounts have not been processed (*why?*) because the Sister-In-Charge was posted here three days ago, is short of three midwives and is still in the process of finding out what is going on.

Where cash is a constraint, it is unlikely that sharps containers or safety boxes will be a priority; they are not regarded as part and parcel of the injection equipment they are designed to hold.

Who is responsible for monitoring how the waste is disposed of? Without proper sharps containers, how would the incinerator operator get the used syringes into the incinerator? When was the last time he fired up the incinerator?

Stripping the needle from the syringe is an attempt to prevent reuse, but the nurse’s hands become contaminated. During the visit we saw student nurses giving injections in the MCH clinic as part of their practical experience. Do the tutors at the nursing school see what is going on in practice? What is their view?

What does the community think about being asked to pay for syringes when the health centre runs out? Do they buy them? From where? How much do they pay? When was the last time this happened?

Where does the trader get his syringes?

Where would you start?

CASE STUDY 4

At the training workshop this health worker was issued with a new steam steriliser for her rural facility. The accompanying kit of syringes and needles filled the rack.

After using the equipment for some time she found that the needles became blunt and the pistons no longer moved easily. She has no forms for requesting fresh needles and syringes; the district storekeeper supplies nothing unless there is a form.

Mothers are less willing to come for necessary injections because of the blunt needles. Now she herself has doubts whether the equipment really works as described at the workshop.

Commentary

All technology depends on **effective operations management**; this technology requires a regular resupply of needles, syringes, TST spots, fuel for the stove, hard water pads, spare parts for the steriliser, and - eventually - a replacement steriliser.

CASE STUDY 5

“The workload for this programme is high and we have to work fast; once you get the knack of these syringes they make the job easier.

When a child needs two shots, it will cry after the first and its mother gets worried; so I fill the syringes first, then I can give both injections quickly.

I put the cap back on the needle after filling each syringe to keep the needle clean and protect it from the flies.

Don't worry if you prick yourself - you'll hardly feel it because the needles are so sharp and you won't get ill because they're all new.

Once you've given the injection, put the cap back on again so that it won't go through the side of this special disposal box that we'll burn later.”

Commentary

This health worker has been supplied with new technologies without training or supervisory support for using them correctly. He is now passing on his unsterile tips to his colleagues. Their injection practices may also pass on blood borne pathogens to their clients.

CASE STUDY 6

Average family size has been dramatically reduced but if more acceptable methods were available, contraceptive prevalence might increase.

Many women prefer an injectable because it is discrete; no supplies need be kept at home, they only have to remember to keep their appointment.

There are rumours that the long-acting injectables make it difficult to become pregnant when you want to.

The new once-a-month injectable solves several of these problems.

Our donors have agreed to fund the extra syringes bundled with safety boxes, for the first two years of the programme.

Commentary

Progress towards one objective may create new problems that have real potential for damaging health. A monthly injectable will double or triple the volume of contaminated waste.

- How will the waste be destroyed?
- Who will pay for disposal?
- Who will pay for supplies in the future?

CASE STUDY 7

One nurse from a busy rural clinic has attended a training course where she learnt how to practise better injection safety. None of the nurse's colleagues nor her supervisor have been on a course for several years.

When she gets back to work, she puts her new knowledge into practice, and tries to explain to her colleagues that changing the needle does not remove the risk of infection.

Added to her colleagues' jealousy about her time off work for the course, she feels that they now regard her as a know-it-all.

Commentary

It is far easier on work relationships to go with the flow. Without regular support and supervision it is difficult for staff to maintain high standards. The supervisor could have asked the nurse to run some updating sessions for other staff, or to suggest ways in which the clinic could improve the safety of injections.

Responsibility can motivate people to do better. Supervisors also need periodic updating of their skills, both technical and managerial.

References and Documents Consulted

- Aylward B *et al.* Risk of human immuno-deficiency virus and Hepatitis B virus transmission through unsafe injections - Model based estimates. Unpublished WHO paper, August 1994.
- Battersby A (1993) *Choosing a Sustainable Policy for Giving Safe Injections in Romania: Final Report.* UNICEF Bucharest: 23 October 1993.
- Battersby A (1995) *Strengthening the Operations Management of South Africa's EPI Programme.* UNICEF Pretoria: April 1995.
- Battersby A (1996) Report on Injection Safety in Eritrea 8-29 June 1996. BASICS Trip Report.
- Battersby A, Ion-Nedelcu N (1996) *Injection Frequency Survey in Romania: Study Findings.* UNICEF Bucharest.
- Becton Dickinson (1997) Penetration Force Evaluation - Cannulae 23 G 1". Unpublished paper.
- BMA (1992) *A Code of Practice for the Safe Handling of Sharps.* British Medical Association Publication.
- DWAF (1994) *Minimum Requirements for the Handling and Disposal of Hazardous Waste.* Department of Water Affairs and Forestry, South Africa: Waste Management Series, Volume 1 (First Edition).
- EPI (1998) *EPI Programme Review 26 April 1998 - 15 May 1998.* Government of the People's Republic of Bangladesh, Ministry of Health and Family Welfare, Directorate of General and Health Services. 26 May 1998.
- Feilden R (1998) *Zambia: Reaching consensus on updating immunization policy within the context of health sector reform, and follow-up activities.* 17 April to 14 May 1998. BASICS Trip Report.
- Fields R (1993) *Preparation of a WHO Regional Plan of Action for the Elimination of Improper Injection and Sterilization Practices.* Manila, Philippines, May 10-21, 1993. Resources for Child Health (REACH) Project Report.
- Grabowsky M, Hadler S, Chen B, Bond W (1993) The risk of transmission of hepatitis B virus or human immuno-deficiency virus from jet injectors or needles and syringes. Unpublished paper (draft).
- Haines A, Donald A (1998) *Getting Research Findings into Practice.* BMJ Books, London.

- Kane AJ, Kane MA, Lloyd J, Zaffran M (1997) Extent of the problem of unsafe injections in the developing world and transmission of blood-borne pathogens - review of the literature and regional estimates. Unpublished WHO paper: August 1997.
- Kane M, McCloy E (1994) *Hepatitis B as an Occupational Hazard*. Viral Hepatitis Prevention Board: European Occupational Health Series No.8. WHO Regional Office for Europe, Copenhagen.
- Levine DP, Sobel JD (1991) *Infections in Intravenous Drug Abusers*. Oxford University Press.
- Lowbury EJJ, Lilly HA., Bull JP (1960) *Disinfection of the hands: Removal of transient organisms* British Medical Journal 2:531-6
- MacLean C (1998) A review of relevant WHO sterilization and disinfection procedures. Unpublished WHO paper: June 1998.
- Picken DJ (1998) A Low Cost Incinerator for Disposing of Hospital Waste in Remote Rural Locations. Unpublished paper, 11 August 1998.
- President's Council Report (1991) "A National Environmental Management System." October 1991. South Africa.
- Romacker M (1998) European Injectable Market. Personal communication.
- Sang N (1997) A Report on the Scientific Literature Regarding Needle and Syringe Sterilization and Disinfection. Unpublished WHO paper: 29 July 1997.
- UNICEF (1992, 1993, 1998) *Copenhagen Warehouse Catalogue Price Lists* (July 1992, July 1993, July 1998). UNICEF Supply Division and Assembly Centre, Copenhagen.
- UNICEF (1998) *Procurement Catalogue (The Blue Book)*. UNICEF Supply Division, Copenhagen.
- WER (1987) Weekly Epidemiological Record 1987, **62**, 345-346.
- WHO (1988) *Guidelines for nursing management of people infected with human immunodeficiency virus (HIV)*. WHO AIDS Series 3. World Health Organization and International Council of Nurses.
- WHO (1994) Report of the 1994 Technet Meeting, Washington 1994.
- WHO (1997) *The case for switching to auto-destruct syringes: Lunchtime Seminar 12.30 September 5 1997*. Unpublished WHO paper.
- WHO (1997) *Product Information Sheets*. WHO/EPI/LHIS/97.01 Also 1998 Edition (draft).
- WPRO/WHO (1998) Progress in improving the safety of injections in the EPI Western Pacific Region. Unpublished paper, 10 September 1998.
- Zaffran M, Lloyd J, Clements J, Stilwell B (1997) *A drive to safer injections*. World Health Organization: GPV/SAGE.97/WP.05.

Feedback on this document will be welcomed at:

FBA@compuserve.com Anthony Battersby or Rachel Feilden,
Riverside Cottage, Tellisford, Bath BA3 6RL, UK

stilwellb@who.ch Barbara Stilwell
WHO, Avenue Appia, 1211 Geneva 27, Switzerland

Annex 1: Options offered by technology

There are two basic choices of technology for giving injections: sterilisables and single-use disposables. Each technology is a part of a system. If part of the system is missing, the technology cannot be used safely.

Injection Equipment

Sterilisable (reusable) syringes, either all-glass or plastic, are used with steel hubbed needles; these are the traditional devices that have been in use for many years. WHO and UNICEF have invested much effort in the development of a range of modern plastic devices and simple sterilising equipment with visible indicators (TST spots) that can help to ensure a sterile product at the point of use. The type tested by WHO is shown on the right



Every health facility must have the ability to sterilise equipment. All or some of the following are common: tongue depressors, forceps, syringes, needles, speculum, forceps, scissors, suture needles, cotton wool, and suture thread.

Sterilising is an activity that lends itself to mass production. Most hospitals have a central sterilising unit that serves all departments. If sterilising drums are used then the activity of sterilising can be separated from providing service. For example instruments can be sterilised in one place and used in another.

Sterilisable devices require the health worker to handle syringes immediately after use, to flush the syringes and needles in clean water and leave them to soak until the staff have time to clean them and resterilise them.



Flushing



Cleaning needles



Cleaning syringes

There are two basic types of sterilising equipment:

- **steam sterilisers**, which are typically used for sterilising syringes and needles and instruments in small clinics.
- **autoclaves**, which create a vacuum before steam is admitted to the chamber to ensure total steam saturation. Autoclaves are typically found in larger facilities and can be used for all items needing sterilisation.



Syringe steam steriliser and stove



General purpose steam steriliser



Autoclave



Cleaning is as important as sterilising. Unless a device is thoroughly cleaned before being placed in a steriliser the sterilising cycle will not succeed in sterilising it. The syringe on the left is encrusted with dirt that will prevent the syringe from becoming sterile.

A study conducted by epidemiologists of an East European country found that 4% of surgical instruments still had dried blood on them after the autoclave's sterilisation cycle was completed.

The second category of medical sharps is disposable devices, developed originally for use in rich countries where

- a) labour costs are high so the cost of sterilising at the point of use is expensive
- b) indigenous manufacturing capacity, skills and investment are present, making it feasible to produce sterile items of the necessary standards locally
- c) systems exist for the safe disposal of contaminated waste.

Within the disposable category there are two distinct types of device:

- 1) the standard, or conventional, disposable syringe, widely manufactured and easily misused;

- 2) devices that have been modified from the conventional disposable either to **prevent their reuse** (autodestruct syringes), or to provide **additional protection to the user** (safety syringes).

The modifications make the autodestruct syringe and the safety syringe more expensive than the conventional disposable (See chapter 7).

If health workers use disposables correctly they do not have to handle the equipment after placing it in the sharps container.

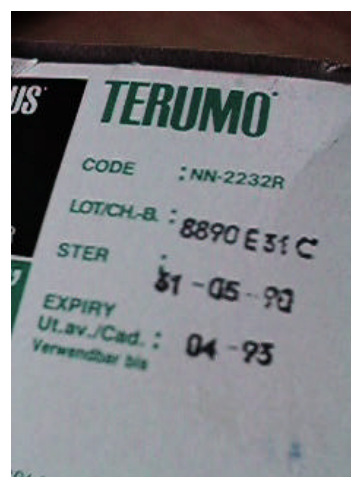
All technologies must have an assured supply system. On a given supply cycle, the storage capacity for disposables must be between 50 and 200 times greater than for sterilisables. Alternatively, if storage space is a constraint then resupply must take place more frequently. The stock control systems must also be well managed to ensure that over-supply does not occur, to avoid the risk that devices will reach their expiry date before they can be used.



Bulk syringe store, grossly over filled

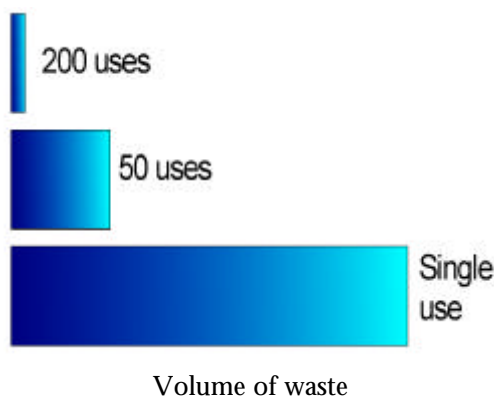


20,000 autodestruct syringes in a clinic. This stock is enough for 2.5 years at the clinic's current workload.



Expired devices in use photographed in 1996

All injections and other sharps generate waste that must be disposed of and destroyed safely. The volume of waste depends on the technology chosen. Sterilisables may be sterilised up to 200 times, or in less favourable environments about 50 times. The volume of waste from sterilisables is dramatically less than from disposables that must be used only once.



The characteristics of the waste are also different.

Before sterilisables are discarded they can be put through a final sterilisation cycle. Traditionally they were made of glass and could be discarded with other waste into conventional dumps.

The modern plastic sterilisable syringe cannot be discarded in this way because it will not rot or degrade naturally; therefore it must be destroyed by burning.

Although sterilisable needles are not contaminated they are still able to cause harm. They must be disposed of safely and this requires that at the time of disposal they

Must be placed in a puncture proof container. These containers, called sharps containers, are made of either cardboard or plastic. The most common sizes available are 5 Litres and 10 Litres. A 5Lt. container will hold: about 100 used 2ml syringes and needles, or 60 used 5ml syringes and needles. The same size container could also hold between 2,000 and 5,000 lancets depending on the type used.



Examples of sharps containers

Used disposables are contaminated and cannot be sterilised because they are made of a different grade of plastic than that used for sterilisable syringes. A disposable syringe will melt at the temperatures required to kill pathogens (see Chapter 3).

Disposables must be disposed of immediately after use by being placed without resheathing or detaching the needle, into a sharps container. There are two principle reasons for this procedure.

First, if the needle is removed there is a risk of residual contaminated fluid inside the syringe spilling onto the health worker's hands; this in turn may result in the next syringe becoming contaminated by the worker.

Secondly, the more the worker handles the used device the greater the risk of needle stick.

Many of the accidents that occur with used sharps come from careless or inappropriate actions immediately after an injection.

Incinerators

The whole incineration process is problematic.

- First, environmentally acceptable incinerators are relatively expensive and devices that comply with the strictest environmental laws and codes of practice are very costly.

- Secondly, no incinerator can satisfactorily burn plastic on its own. The waste fed into the incinerator must be a mixture, typically one part (by weight) of high calorific waste (plastic) and three parts of other lower calorific waste such as paper, bandages, wrappers and swabs, which can also act as a wick to absorb the molten plastic until it has burnt.
- Thirdly, moving contaminated waste requires a management system as sophisticated as that for moving pharmaceuticals, and which can account for all the items handled.

The following table shows the time needed to burn anticipated sharps waste from sterilisable and disposable systems, taking into account all the requirements for environmentally acceptable incineration. Even when an incinerator is burning cleanly it still emits carbon dioxide, which is the major greenhouse gas, and so the incineration process is a contributor to global warming.

An illustration of the waste volumes

Based on a country of 40 million people where 120 million injections are administered each year

Sterilisables			Disposables		
Annual volume of syringes	Annual volume of LCV waste ¹	Incineration load ²	Annual volume of syringes	Annual volume of LCV waste ¹	Incineration load ²
45-175m ³	135-525m ³	63-245 days	8,800 m ³	26,400m ³	12,300 days

1. LCV= low calorific value. The volume of LCV waste required to balance the high calorific value plastic and enable the incinerator to burn correctly.
2. Days for an incinerator with capacity to burn 220Kg/hour.

Destruction

The satisfactory destruction of clinical and sharps waste is one of the biggest problems facing health services today. Much research and development is being invested in finding safer ways to administer injections, including technologies for administering doses without a conventional needle. However, very little has yet been done to find inexpensive ways of destroying clinical and sharps waste.

The principles of safe incineration are summarised by **TTT**:

- **Time:** long enough for complete combustion
- **Temperature:** between 800°C and 1,000°C
- **Turbulence:** The process of completely mixing oxygen with the volatiles released in the combustion chamber which is essential if complete incineration is to be achieved.

For an incinerator to work efficiently it must be loaded with a mix of waste. Each type of waste has a different calorific value, which is described as the General Refuse Equivalent (GRE).

- Plastic has a high calorific value and its GRE is 3.
- Bandages are organic waste with a low calorific value; the GRE of such organic waste is 1.

The GRE scale indicates to the incinerator operator the proportions (by weight) in which different types of waste must be combined in order to achieve safe and effective incineration. Plastic must be mixed with three times its weight of organic waste, such as bandages. To mix waste correctly, it must be segregated at source. The minimum segregation is into three categories:

1. Sharps in a puncture proof container (Sharps box)
2. Clinical waste into yellow or red plastic bags
3. General waste into black or green plastic bags

From this it should be clear that incinerator operators need training, a manual, and scales.

The following are examples of small and medium sized incinerators that might be suitable for the destruction of used sharps. The larger one in the centre is suitable for a bedded health centre or small hospital and is available now. The smaller ones on the left and the right are expected to begin field trials shortly.



This model is specifically designed for the destruction of sharps boxes. It uses a vortex ventilation system to reach temperatures in excess 1,000°C. At the same time it is so well insulated that it remains cool to the touch and so can be installed inside a facility. It is expected to start field trials shortly.



At smaller facilities there is no reason why the incinerator could not be a part of the clinic's equipment, especially if it can be used inside the clinic or has a secondary function such as generating hot water. A prototype incinerator-cum-hot water generator is illustrated on the right. The person is measuring the temperature of the water (97°C).

Alternatives to Incineration

There are alternatives to incineration; these include:

Sterilising and shredding where the sharps are sterilised by heat or chemicals and then shredded so that their volume is reduced. This waste can then be sent to an approved landfill. The process does require electricity and properly prepared landfill sites. It is efficient in large volume.

Plasma Enhanced Melting is not incineration - it does not require air; it is essentially an anaerobic process, using only the oxygen derived from the breakdown of water to oxidise silica and metals into glass. It transforms waste into highly stable, inert, glass-like material, recoverable metals, and hydrogen-rich gas (which can directly fuel a multi-fuel diesel generator to supply electricity to run the process). For many organic wastes, the volume of residue remaining after processing is less than 5 percent of the volume of the original waste. This chemical process is much more efficient than the heat-transfer process used in standard incinerators. However it is more expensive than simple incineration and does require electricity and resupply of consumable supplies (carbon rods).

**Injection technologies that are currently available:
What are the best options for your circumstances?**

A: Conventional Disposable Syringes

Description:

Designed for a single use; an all-plastic syringe with steel needle (usually separate).

Reasons to use:

- Sterilised by the manufacturer
- Less costly than autodestruct syringe
- Available in multiple combinations of syringe size and needle size

Reasons not to use:

- More costly per injection than sterilisable syringe
- Easy to re-use; staff may change needle between patients; impossible to re-sterilise
- It has a market value and sold to unqualified customers, who have little understanding of the risks attached to its use.
- volume of waste greatly exceeds that for sterilisables

B: Sterilisable Syringes

Description:

Either all-plastic or all-glass syringe with steel needle, designed to be re-used after proper cleaning and sterilisation in a steam steriliser or autoclave; available in multiple combinations of syringe size and needle size.

Reasons to use:

- The least expensive option per injection
- Lowest volume for re-supply and for waste disposal
- Correct sterilisation cycle can be demonstrated to clients by use of the TST spots (time, steam, temperature)

Reasons not to use:

- Sterilisation is an extra procedure and depends on health worker diligence and the supply system (*e.g. fuel, steriliser spare parts, TST spots*)
- Exposes health worker to greater risk when cleaning the used syringes
- The needles are less sharp than the other options

C: Safety Syringes

Description

Modified disposable plastic syringe, designed so that the health worker can disable it in such a way that the needle is protected and cannot be re-used.

Reasons to use:

- Sterilised by the manufacturer
- Helps protect health and ancillary staff against needle stick
- Helps protect management against legal claims

Reasons not to use:

- The most expensive option per injection
- Volume of waste greatly exceeds that for sterilisables
- The safety mechanism relies on the user

D: Autodestruct Syringes

Description:

Specially modified disposable syringe with fixed needle which is automatically disabled after a single use; at present available in 1.0ml, 0.5ml and 0.05ml sizes

Reasons to use:

- Sterilised by the manufacturer
- Needle and syringe can be used only once
- Low wastage of the injectable product
- Fast to use once health workers are trained

Reasons not to use:

- More costly than sterilizables and conventional disposables
- Volume of waste greatly exceeds that for sterilisables
- Fixed needles add complexity to procurement and stock management

Annex 2: Cost Estimates

In order to illustrate some of the financial implications of strategic choices, we have estimated the costs of using disposable technologies and compared these with the costs of sterilisable technologies. In 2.1 the basic assumptions underlying the cost estimates are described. In 2.2 the results of the sensitivity analysis - varying these assumptions - are shown.

2.1 Assumptions underlying the cost estimates

The **profile of activity** is based on services provided, including:

- ◇ curative treatments (at a rate of 1.9 injections per capita per year),
- ◇ diagnostic procedures (0.4 per capita per year),
- ◇ immunisation; the schedule is assumed to include hepatitis B vaccine (with coverage levels between 98% for BCG and 85% for TT),
- ◇ family planning (with coverage assumptions for three different injectables),
- ◇ other parenteral procedures at the rate of 0.4 per capita per year.

The **mix** of injection equipment (proportion of syringes of each size, proportion of needles of each size) is based on programme guidelines (EPI and family planning) and on data collected from three countries.

Most of the **prices** for needles, syringes and lancets are from UNICEF's Blue Book; the standard service charge (8%) has been added. Other prices are from WHO's Product Information Sheets; for some products there is a wide range in prices from different suppliers (e.g. prices of single rack steam sterilisers vary by a factor of three). In these cases the average price has been used.

For **equipment** it is assumed that each "health unit" serves a population of 5,000. This assumption is conservative; the model assumes that urban clinics with larger catchment populations are equipped by buying more of the standard clinic issue. In practice economies of scale could be attained by choosing equipment to suit the workload (e.g. triple rack sterilisers with six or more drums, or larger autoclaves with multiple drums).

A **freight charge** of 10% has been added to all ex works prices to obtain a notional DDP cost (goods paid for, delivered and duty paid).

Table 3 illustrates the cost for one million parenteral procedures under these assumptions, comparing sterilisable technologies with disposable technologies (standard disposables).

The illustrated costs indicate the comparative level of financing that must be committed year after year to ensure sufficient supplies for safe injections.

Other costs that do not appear in Table 3 include:

- * staff time,
- * fuel for heating sterilisers and incinerating waste, and
- * the cost of storing and distributing supplies.

Table 3 Illustration of costs for supplies and equipment, per million parenteral procedures for two strategies: sterilisables and standard disposables

Item	Sterilisables/million PPs ^a		Disposables/ million PPs ^a
	33% of uselife ^b	100% of uselife ^b	
Needles, syringes and lancets	\$8,275	\$2,758	\$63,933
Equipment for steam sterilisation ^c	\$6,701	\$2,581	\$0
Sharps containers for disposal ^d	\$184	\$61	\$11,674
Total	\$15,160	\$5,402	\$75,607

- a Costs per million parenteral procedures (including lancets).
- b The expectation is that sterilisable needles could be used 50 times, sterilisable syringes could be used 200 times, and sterilisable lancets could be used 100 times; this would be 100% of their useful life (last column). The column headed “33% of uselife” illustrates the costs if sterilisable needles were discarded after 17 uses, sterilisable syringes were discarded after 67 uses, and sterilisable lancets were discarded after 33 uses.
- c Includes steam sterilisers, stoves, forceps, TST spots, hard water pads, and spare parts (used at a rate from recorded experience). The first three items have been amortised over a uselife of 10 years with a discount rate of 10%.
- d These costs do not include incinerating or destroying the sharps containers when they have been filled with contaminated waste.
- e This figure is inconsistent with a holistic approach to safe practice; every clinic where wounds are dressed or speculums used must be equipped with sterilising equipment.

2.2 What if ...? Selected sensitivity analyses

2.2.1 Reducing the useful life of sterilizable equipment

A single rack for immunization equipment holds 42 needles and syringes; it is usual to sterilize a full rack during each sterilization cycle. In settings where the number of injections given from each sterilisation cycle is very low, the useful life of sterilisable equipment is reduced. Under the current set of assumptions, a strategy of using sterilisables would still be less costly (in terms of financial allocations) than one relying on disposables if:-

- sterilisable needles were used for at least 4 injections,
- sterilisable syringes were used at least 13 times, and
- sterilisable lancets were used at least 7 times

before being discarded. These levels of use represent 6.5% of the expected useful life advertised for these items.

2.2.2 Substituting autodestruct syringes for standard disposable syringes

Substituting autodestruct syringes (with their fixed needles) for conventional disposable syringes of 0.5ml, 1ml and 2ml adds 59% to the cost of one million parenteral procedures in the present model. This large cost difference is due to the price differential, especially on the 2ml size; prices are expected to fall as more manufacturers enter the market.

2.2.3 Costs of ameliorating the effects of hard water

Hard water adds enormously to the costs of sterilisation. It damages sterilisable syringes and needles (see Section 4.2.6) so they have to be replaced before fulfilling their expected workload. The model above includes hard water pads, which are also costly; if they can be replaced by a vapour purifier the savings from extending the useful life of the injection equipment will soon cover the initial outlay on the vapour purifier.

2.2.4 Economies from central sterilisation

If it is feasible to use drums (as described in Section 4.2.6) then the strategy of central sterilisation in triple rack steam sterilisers or larger autoclave equipment offers opportunities not only for financial savings, but also for improving the quality of services provided.

